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Proposed Registration Decision PRD2013-15

Dichlorprop-P

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Overview

Registration Decision for Dichlorprop-P

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of A H Marks 2,4-DP-P 2EH Ester (Technical) and A H Marks 2,4-DP-P Technical Acid, Optica Trio containing the technical grade active ingredients MCPA, dichlorprop-P and mecoprop-P to control broadleaf weeds in wheat (spring, durum and winter), barley and oats and Estaprop XT Liquid Herbicide containing the technical grade active ingredients dichlorprop-P and 2,4-D (both present as 2-ethylhexyl ester) to control broadleaf weeds and brush in wheat (spring, durum and winter), barley and on industrial and non-crop land.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of A H Marks 2,4-DP-P 2EH Ester (Technical) and A H Marks 2,4-DP-P Technical Acid, Optica Trio and Estaprop XT Liquid Herbicide.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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[1] "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

[2] "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Dichlorprop-P?

Dichlorprop, also known as 2,4-DP, is currently registered in Canada. Dichlorprop exists in an equal ratio of two isomeric forms: R(+) and S(-). Only the R(+) isomer exhibits herbicidal properties, this isomer is known as Dichlorprop-P or 2,4-DP-P. Three forms; 2,4-DP-P acid, 2,4-DP-P dimethylamine salt (2,4-DP-P DMAS), and 2,4-DP-P ethylhexyl ester(2,4-DP-P EHE), are represented as Dichlorprop-P (2,4-DP-P) unless otherwise stated in this document.

Estaprop XT Liquid Herbicide contains the active ingredients dichlorprop-P ethylhexyl ester and 2,4-D ethylhexyl ester which both belong to the phenoxy herbicide family. Phenoxy herbicides are growth regulator herbicides, which mimic natural growth hormones, inducing rapid uncontrolled growth in broadleaf plants which eventually kills the plants. Estaprop XT Liquid Herbicide is a post-emergence herbicide. It is to be used on spring wheat, durum wheat, winter wheat, barley and non-agricultural areas such as: roadsides, utility lines, railway rights-of-way, non-crop land and brush control.

The active ingredients in Optica Trio consists of dimethylamine salts of dichlorprop-P, MCPA and mecoprop-P which all belong to the phenoxy herbicide family. Optica Trio is a post-emergence herbicide, applied to wheat (spring, durum and winter), barley, and oats, using ground application equipment, to control a range of broadleaved weeds.

Health Considerations

Can Approved Uses of Dichlorprop-P Affect Human Health?

2,4-dichlorprop-P is unlikely to affect health when used according to label directions.

Potential exposure to 2,4-DP-P may occur through the diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses considerably higher than levels to which humans are normally exposed when 2,4-DP-P salt and 2,4-DP-P EHE products are used according to label directions.

Technical 2,4-DP-P acid and 2,4-DP-P EHE are moderately acutely toxic by the oral route, but are of low acute toxicity by the dermal and inhalation routes of exposure. The acid is extremely irritating to the rabbit eye affecting the cornea, while the eye irritation potential of the ester form of 2,4-DP-P was minimal. The difference in eye irritation potential might be related to the physical form of the acid (solid) and ester (liquid) as the solid acid form might cause mechanical injury when instilled into the eye. Both the acid and ester forms of 2,4-DP-P were only slightly irritating to the rabbit skin. Although 2,4-DP-P is not a skin sensitizer, the ester is a skin sensitizer when tested in the guinea pig using the maximization method. Based on the acute toxicity data, the following label statements are displayed on the technical product labels: **WARNING – POISON** for both 2,4-DP-P acid and 2,4-DP-P EHE; **DANGER – CORROSIVE TO EYES** for 2,4-DP-P acid; and **POTENTIAL DERMAL SENSITIZER** for 2,4-DP-P EHE.

Optica Trio, an end-use product containing 2,4-DP-P, is slightly acutely toxic by the oral route, but is of low toxicity by the dermal and inhalation routes of exposure. The formulation is extremely irritating to the rabbit eye, but is only slightly irritating to the rabbit skin. Optica Trio is not a dermal sensitizer when tested in the guinea pig using the maximization protocol. Based on the acute toxicity data, the following label statements are displayed on the product labels: **CAUTION – POISON** and **DANGER – CORROSIVE TO EYES**.

The end-use product Estaprop XT Liquid Herbicide is moderately acutely toxic by the oral route, but is of low acute toxicity by the dermal and inhalation routes of exposure. The formulations are minimally irritating to the eye or skin and is not skin sensitizer. Based on the acute oral toxicity data, the following label statements are displayed on the product labels: **WARNING – POISON**.

In vivo and in vitro studies demonstrated that the 2,4-DP-P EHE is readily converted to 2,4-DP-P acid. Available bridging data indicated that the toxicity potential of 2,4-DP-P and 2,4-DP-P EHE is similar.

Both 2,4-DP-P acid and 2,4-DP-P EHE are not genotoxic, carcinogenic, neurotoxic, or teratogenic.

The first signs of toxicity in animals given daily doses of 2,4-DP-P acid or 2,4-DP-P 2-EHE over longer periods of time were effects on the liver, kidneys, and red blood cells (anemia). Observations in dogs at high doses also included diarrhoea and gastro-intestinal ulcers.

When 2,4-DP was given to pregnant rats, effects on reproduction and offspring survival were observed at doses that were also toxic to the maternal animals, indicating that the fetus is not more sensitive to 2,4-DP than the adults.

The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occur in animal studies.

Residues in Water and Food

Dietary risks from food and water are not of concern

Aggregate dietary intake estimates, which include exposure from food plus drinking water, revealed that the general population and infants (the subpopulation which would ingest the most dichlorprop-P relative to body weight) are expected to be exposed to less than 3.3% of the acceptable daily intake. Similarly for the acute dietary exposure, the aggregate intake estimate (food plus water) for the general population is 9.2% of the acute reference dose and for the highest exposed sub-population, children 1-2 years old, the aggregate intake estimate is 14.7% of the acute reference dose. Based on these estimates, the acute and chronic dietary risk from dichlorprop-P is not of concern for all population subgroups. Dichlorprop-P is not carcinogenic; therefore, a cancer dietary risk assessment is not required.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act.* Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout Canada using dichlorprop-P on wheat, barley and corn were acceptable. The MRLs for this active ingredient can be found in the Science Evaluation section of this Consultation Document.

Risks in Residential and Other Non-Occupational Environments

No residential and/or other non-occupational uses were requested. The product application directions on the label include statements to minimize spray drift. Thus, exposure health risks for bystanders in these environments are expected to be negligible.

Occupational Risks From Handling Optica Trio and Estaprop XT Liquid Herbicide

Occupational risks are not of concern when used according to the label directions, which include protective measures.

Farmers and commercial applicators when mixing, loading and applying as well as field workers re-entering freshly treated areas can come in direct contact with 2,4-DP-P residues on the skin or by inhalation. Therefore, the label specifies that anyone mixing/loading and applying must wear protective clothing and equipment. The label also requires that workers do not enter treated fields for 12 hours after application. These precautionary risk reduction measures are for all active ingredients in these products. Taking into consideration the Key Risk-Reduction Measures specified in the section below, the number of applications and the expected exposure period for workers, the occupational risks are not a concern.

The occupational exposure and health risks from handling 2,4-D, MCPA and Mecoprop-P in the above end-use products are not of concern when these end-use products are used according to the label directions, which include protective measures, and as stipulated in the following Re-evaluation Decision Documents:

- Proposed Acceptability for Continuing Registration PACR2007-06, *Re-evaluation of the Agricultural, Forestry, Aquatic and Industrial Site Uses of (2,4-Dichlorophenoxy)acetic Acid [2,4-D];*
- Re-evaluation Decision document RVD2008-11, *(2,4-dichlorophenoxy) acetic acid [2,4-D]*;
  Proposed Re-evaluation Decision PRVD2007-01, *The agricultural, forestry and industrial uses of the herbicide (4-chloro-2-methylphenoxy) Acetic Acid (MCPA)*;
- Re-evaluation Decision RVD2008-20, *(4-chloro-2-methylphenoxy) Acetic Acid (MCPA)*; and
- Re-evaluation Decision RRD2004-09, *Mecoprop.*

Environmental Considerations

What Happens When Dichlorprop-P Is Introduced Into the Environment?

Dichlorprop-P is non-persistent with the main route of transformation in the terrestrial environment being biotransformation in soil. Dichlorprop-P is not expected to volatilise although it has the potential to leach to groundwater and in some circumstances may eventually flow into surface water. No major transformation products of dichlorprop-P were identified in aerobic soil laboratory studies. Dichlorprop-P can enter the aquatic environment through spray drift and runoff from treated fields. In aquatic systems, dichlorprop-P transforms rapidly via phototransformation and biotransformation to a number of minor transformation products.

The risk to the environment was assessed for the dichlorprop-P end-use products, Estaprop XT Liquid Herbicide and Optica Trio. In the terrestrial environment, Estaprop XT Liquid Herbicide and Optica Trio at the proposed application rate and use pattern, may pose a risk to vascular plants, and predatory and parasitoid insects. These risks may be mitigated by applying spray buffer zones and other label statements. No risk was identified to earthworms, bees or birds.

In the aquatic environment Estaprop XT Liquid Herbicide and Optica Trio, at the proposed application rate and use pattern, are not expected to pose a risk to freshwater and marine aquatic invertebrates, fish and amphibians on an acute or chronic basis. A risk to freshwater algae and vascular plants was identified from exposure to runoff and drift. The risks identified from drift are mitigated by applying spray buffer zones and label statements. To reduce the potential risk from runoff, advisory statements are included on the label.

Value Considerations

What is the Value of Estaprop XT Liquid Herbicide?

Estaprop XT Liquid Herbicide controls a range of broadleaved weeds in wheat (spring, durum and winter), barley and non-agricultural areas such as: roadsides, utility lines, railway rights-of-way, non-crop land. This product is also used for brush control. Estaprop XT Liquid Herbicide is compatible with integrated weed management practices, conservation tillage, and conventional crop production systems. Estaprop XT Liquid Herbicide is applied after weed emergence, allowing growers to better assess whether the herbicide is suitable for the particular weed species present.

What is the Value of Optica Trio?

Optica Trio provides effective control of a range of broadleaved weeds in wheat (spring, durum and winter), barley and oats. Optica Trio is compatible with integrated weed management practices, conservation tillage, and conventional crop production systems. Optica Trio is applied after weed emergence, allowing growers to better assess whether the herbicide is suitable for the particular weed species present.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Estaprop XT Liquid Herbicide and Optica Trio to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with 2,4-DP-P, and other active ingredients in the end-use products, on the skin or through inhalation of spray mists, anyone mixing, loading and applying must wear the recommended PPE as noted below.

Technical 2,4-DP-P acid and 2,4-DP-P EHE

Based on the acute toxicity data, the following label statements are displayed on the technical product labels: **WARNING – POISON** for both 2,4-DP-P acid and 2,4-DP-P EHE; **DANGER – CORROSIVE TO EYES** for 2,4-DP-P acid; and **POTENTIAL DERMAL SENSITIZER** for 2,4-DP-P EHE.

For Estaprop XT Liquid Herbicide

Handling the concentrate (mixing/loading) for all scenarios: Mixers/loaders must wear coveralls over a long-sleeved shirt, long pants and chemical-resistant gloves, socks and shoes and protective eye wear (face shield or safety glasses). Rinse gloves before removal. When handling more than 660 L of this product per day workers must also use a closed system.

Application using ground or aerial equipment: Applicators must wear coveralls over a long-sleeved shirt and long pants, socks and shoes. Chemical-resistant gloves must also be worn during clean-up and repair activities. Rinse gloves before removal. Gloves are not required during application when applicator is in an enclosed tractor or an enclosed airplane cockpit.

Application using handheld equipment: Applicators must wear coveralls over a long sleeved shirt, long pants and chemical-resistant gloves. Mixers/loaders/applicators using handheld equipment must wear a respirator if they will be handling more than 12.5 L of this product per day. DO NOT handle more than 20 L of this product per day.

Apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and recreational areas is minimal. Take into consideration wind speed, wind direction, temperature, application equipment and sprayer settings.

No human flaggers are permitted for aerial applications.

Re-entry is not permitted until 12 hours after application to all agricultural scenarios.

Based on the acute oral toxicity data, the following label statements are displayed on the product labels: **WARNING – POISON**.

For Optica Trio Broadleaf Herbicide

Apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and recreational areas is minimal. Take into consideration wind speed, wind direction, temperature, application equipment and sprayer settings.

Re-entry is not permitted until 12 hours after application.

Based on the acute toxicity data, the following label statements are displayed on the product labels: **CAUTION – POISON** and **DANGER – CORROSIVE TO EYES**.

Environment

Mitigative measures are required to protect sensitive terrestrial and aquatic habitats from the use of dichlorprop-P. These mitigative measures include precautionary statements on the label regarding environmental hazards and the directions for use as well as appropriate buffer zones to protect sensitive habitats from spray drift.

Next Steps

Before making a final registration decision on dichlorprop-P, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please note that, to comply with Canada's international trade obligations, consultation on the proposed MRLs will also be conducted internationally via a notification to the World Trade Organization. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

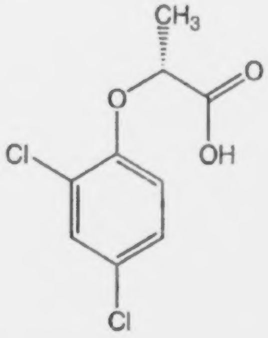
When the PMRA makes its registration decision, it will publish a Registration Decision on dichlorprop-P (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Dichlorprop-P

1.0 The Active Ingredient, Its Properties and Uses

1.1.1 Identity of the Active Ingredient Dichlorprop-P

Active substance	Dichlorprop-P
Function	**Herbicide**
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	(R)-2-(2,4-dichlorophenoxy)propionic acid
2. Chemical Abstracts Service (CAS)	(+)-2-(2,4-dichlorophenoxy)propanoic acid
CAS number	15165-67-0
Molecular formula	$C_9H_8Cl_2O_3$
Molecular weight	235.1
Structural formula	
Purity of the active ingredient	92.5%

1.1.2 Physical and Chemical Properties of the Active Ingredient and End-Use Product

Technical Product—Dichlorprop-P Technical

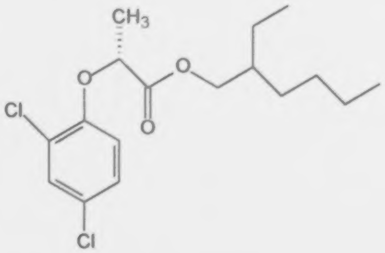
Property	Result
Colour and physical state	White solid
Odour	Burned, phenol-like acrid
Melting range	109.5–120.0°C
Boiling point or range	N/A
Specific gravity	1.435
Vapour pressure at 20°C	Not measurable. Estimated values by extrapolation: 0.05 Pa at 20°C and 0.09 Pa at 25°C
Ultraviolet (UV)-visible spectrum	Solvent — λ max (nm) distilled water — 227 and 282 0.1 M HCl — 224 and 280 0.1M NaOH — 228 and 282 No absorption maxima at wavelengths greater than 300 nm.
Solubility in water at 20°C	Solvent — Solubility (g/L) purified water — 0.604 pH 3 — 0.5 pH ≥ 9 — >500
Solubility in organic solvents at 20°C (g/100 mL)	Solvent — Solubility (g/L) acetone — 1832 dichloromethane — 326 hexane — 1.6
n-Octanol-water partition coefficient (K_{ow})	pH — log K_{ow} 4 — 1.89 7 — -0.619 9 — -0.897
Dissociation constant ($\mathrm{p}K_a$)	2.41
Stability (temperature, metal)	Stable at 21°C & 54°C Stable in the presence of iron aluminium & tin

End-Use Product—Optica Trio

Property	Result
Colour	Reddish yellow
Odour	Phenolic-like smell
Physical state	Clear liquid
Formulation type	Solution
Guarantee	Dichlorprop-P (present as dimethylamine salt), 310 g/L MCPA (present as dimethylamine salt), 160 g/L Mecoprop-P (present as dimethylamine salt), 130 g/L
Container material and description	High density polyethylene, 1, 5, 10 and 20 L
Density	1.175 g/mL

Property	Result
pH of 1% dispersion in water	8.1 (1% solution)
Oxidizing or reducing action	The product is not expected to possess any oxidizing properties.
Storage stability	The product is shown to be stable for two years under warehouse conditions.
Corrosion characteristics	No corrosion of the containers was noticed under warehouse storage conditions.
Explodability	The product is not explosive.

1.1.3 Identity of the Active Ingredient Dichlorprop-P 2-EHE

Active substance	Dichlorprop-P 2-EHE
Function	Herbicide
Chemical name	
1. **International Union of Pure and Applied Chemistry (IUPAC)**	, 2-ethylhexyl ester (R)-2-(2,4-dichlorophenoxy)propanoate
2. **Chemical Abstracts Service (CAS)**	, 2-ethylhexyl ester (R)-2-(2,4 dichlorophenoy)propanoate
CAS number	enantiomer 865363-39-9
Molecular formula	$C_{17}H_{24}Cl_2O_3$
Molecular weight	347.3
Structural formula	
Purity of the active ingredient	62.3% (expressed as dichlorprop-P acid)

1.1.4 Physical and Chemical Properties of the Active Ingredient and End-Use

Technical Product—Dichlorprop-P 2-EHE Technical

Property	Result
Colour and physical state	Orange liquid
Odour	Phenolic (aromatic)
Melting range	N/A
Boiling point or range	>310°C (decomposed)
Density	1.1262 g/mL at 20°C
Vapour pressure at 20°C	5.4×10^{-4} Pa
Ultraviolet (UV)-visible spectrum	Solvent — λmax (nm) Distilled water — 227 and 282 0.1M HCl — 224 and 280 0.1M NaOH — 228 and 282 No absorption at wavelengths greater than 300 nm.
Solubility in water at 20°C	Insoluble in neutral, acidic and basic media
Solubility in organic solvents at 20°C (g/100 mL)	>1000 g/L in methanol, octanol, ethyl acetate, dichloromethane, heptane, acetone and toluene
n-Octanol-water partition coefficient (K_{ow})	pH — log K_{ow} 5 — ≥3.755 7 — ≥3.809 9 — ≥3.844
Dissociation constant (pK_a)	The product does not dissociate in water.
Stability (temperature, metal)	Stable at 54°C. Stable in the presence of iron, aluminum and tin.

End-Use Product—Estaprop XT Liquid Herbicide

Property	Result
Colour	Dark amber
Odour	Paint-solvent like smell
Physical state	Liquid
Formulation type	Emulsifiable concentrate
Guarantee	Dichlorprop-P (present as 2-ethylhexyl ester), 210 g/L 2,4-D (present as 2-ethylhexyl ester), 400 g/L
Container material and description	Plastic drums or tanks, 1 – 450 L
Density	1.1 g/mL
pH of 1% dispersion in water	3.6
Oxidizing or reducing action	The product is neither an oxidizing nor a reducing agent.
Storage stability	The EP has been found to be stable for 1 year under ambient conditions in a commercial container.
Corrosion characteristics	No corrosion was observed during 1 year commercial storage.
Explodability	The product is not expected to be explosive.

1.2 Directions for Use

1.2.1 Estaprop XT Liquid Herbicide

Estaprop XT Liquid Herbicide is a selective herbicide for use as a post-emergence treatment on wheat (spring, durum and winter), barley and non-agricultural areas such as: roadsides, utility lines, railway rights-of-way, and non-crop land for the control of a wide range of broadleaved weeds. It is also used for brush control. The product is to be applied at a rate of 0.73 - 7.3 kg a.i./ha (1.2 to 12 L/ha) depending on the use and the weeds that are present (Table 1.3.1). It may be applied as a broadcast treatment on cereals and for non-agricultural areas with ground or aerial application equipment. For brush control, this product would be applied as a spot treatment. Estaprop XT Liquid Herbicide may be applied once per growing season.

Table 1.2.1 Weed Control Claims for Estaprop XT Liquid Herbicide

Use-Site	Herbicide Rate	Weeds Controlled
Cereal Crops	0.73 kg a.i./ha or 1.2 L/ha	annual sow-thistle, ball mustard, blue bur, burdock, Canada thistle (top-growth only), cocklebur, curled dock (top-growth only), dog mustard, flixweed, hare's ear mustard, Indian mustard, kochia, lady's-thumb, lamb's-quarters, night-flowering catchfly, oak-leaved goosefoot, perennial sow-thistle (top-growth only), ragweed, redroot pigweed, round-leaved mallow, Russian pigweed, Russian thistle, shepherd's purse, smartweed, stinkweed, stork's-bill, tartary buckwheat, tumble mustard, volunteer rapeseed (canola), volunteer sunflower, wild buckwheat, wild mustard, wormseed mustard, and toadflax (suppression)
Industrial and non-crop uses	1.7 kg a.i./ha or 2.8 L/ha	alfalfa, bull thistle, burdock, buttercup, Canada thistle, chicory, cinquefoil, curled dock, dandelion, dogbane, goat's-beard, goldenrod, hawkweed, horsetail (partial control), milkweed (topkill), mullein, plantain, perennial sow-thistle, sweet clover, tansy, teasel, toadflax, vetch, wild carrot, and yellow rocket
Brush control - low rate	2.7-5.5 kg a.i./ha or 4.5-9 L/ha	buckbrush, hawthorn, poplar, scotch pine, sugar maple, white cedar, wild cherry, wild plum, and wild raspberry
Brush control - high rate	3.7-7.3 kg a.i./ha or 6-12 L/ha	alder, aspen, basswood, balsam fir, birch, bur oak, blueberry, elderberry, elm, ground juniper, hardhack, hazel, hickory, honeysuckle, Manitoba maple, poison ivy, raspberry, red pine, rose (some regrowth), silver maple, sugar maple (some regrowth), sumac, tamarack, white oak, wild apple, and willow

Estaprop XT Liquid Herbicide may be applied at a rate of 0.73 kg a.i./ha (1.2 L/ha) in tank-mix with several grass herbicides in cereal crops: Achieve Liquid Herbicide (registration number 27011), Assert 300 SC Herbicide (registration number 21032), Avenge 200-C Wild Oat Herbicide (registration number 18555), Everest Solupak 70 DF Herbicide (registration number 26448), Horizon 240EC Herbicide Tank Mix (registration number 24076), and Puma^{120} Super (registration number 25864). For brush control Estaprop XT Liquid Herbicide, at an application rate of 2.6-5.2 kg a.i./ha (4.2-8.4 L/ha), can be tank-mixed with Vanquish Herbicide (dicamba) (registration number 26980).

1.2.2 Optica Trio

Optica Trio is a selective herbicide for use as a post-emergence treatment on wheat (spring, durum and winter), barley and oats for the control of a wide range of broadleaved weeds. The product is to be applied at a rate of 900 or 1500 g a.i./ha (1.5 or 2.5 L/ha) depending on the broadleaf weeds that are present (Table 1.2.2), as a broadcast treatment with ground application equipment only. Optica Trio may be applied once per growing season with a maximum application rate of 1500 g a.i./ha.

Table 1.2.2 Weed Control Claims for Optica Trio

Herbicide Rate	Weeds Controlled	Weeds Suppressed
900 g a.i./ha or 1.5 L/ha	stinkweed, wild mustard, lamb's-quarters, volunteer canola	
1500 g a.i./ha or 2.5 L/ha	common chickweed, wild buckwheat, redroot pigweed, kochia, common ragweed, cleavers[1]	lady's thumb Canada thistle (top growth suppression)

[1] Cleavers: Spray in 1-2 whorl stage

Optica Trio may be applied at a rate of 900 or 1500 g a.i./ha (1.5 or 2.5 L/ha) in tank mix with Horizon 240EC Herbicide Tank Mix at 56 g a.i./ha (230 mL/ha) to control broadleaf weeds listed on the Optica Trio label plus wild oats, green foxtail and yellow foxtail in spring wheat only.

Optica Trio may be applied at a rate of 900 or 1500 g a.i./ha (1.5 or 2.5 L/ha) in tank mix with Everest Solupak 70 DF (registration number 26448) at 30 g a.i./ha (43 g/ha) to control broadleaf weeds listed on the Optica Trio label plus wild oats and green foxtail in spring wheat. Optica Trio may also be applied at a rate of 900 or 1500 g a.i./ha (1.5 or 2.5 L/ha) in tank mix with Everest Solupak 70 DF at 15 g a.i./ha (21.5 g/ha) to control broadleaf weeds listed on the Optica Trio label plus green foxtail only in spring wheat.

1.3 Mode of Action

Estaprop XT Liquid Herbicide contains the active ingredients dichlorprop-P and 2,4-D ester which both belong to the phenoxy herbicide family and is classified as a Group 4 Herbicide (refer to Regulatory Directive DIR99-06, *Voluntary Pesticide Resistance-Management Labelling Based on Target Site/Mode of Action*, for details). Phenoxy herbicides are growth regulator herbicides, which mimic natural growth hormones, inducing rapid uncontrolled growth in broadleaf plants which eventually kills the plants.

Optica Trio contains the active ingredients dichlorprop-P, MCPA and mecoprop-P which all belong to the phenoxy herbicide family and is classified as a Group 4 Herbicide (refer to Regulatory Directive DIR99-06, *Voluntary Pesticide Resistance-Management Labelling Based on Target Site/Mode of Action*, for details). Phenoxy herbicides are growth regulator herbicides, which mimic natural growth hormones, inducing rapid, uncontrolled growth in broadleaf plants which eventually kills the plants.

2.0 Methods of Analysis

2.1 Dichlorprop-P

2.1.1 Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredient and the impurities in Dichlorprop-P Technical have been validated and assessed to be acceptable for the determinations.

2.1.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulations has been validated and assessed to be acceptable for use as an enforcement analytical method.

2.1.3 Methods for Residue Analysis

The analytical methods developed for determination of dichlorprop-P, its ethylhexyl ester and their transformation products in soil have been validated and determined to be acceptable for post-registration monitoring methods.

Gas chromatography methods with mass spectrometric detection (GC-MSD; Method AR 258-00 in cereal matrices and Method AR 125-96 in animal matrices) were developed and proposed for data generation and enforcement purposes. These methods fulfilled the requirements with regards to specificity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries (70–120%) were obtained in plant and animal matrices.

2.2 Dichlorprop-P 2-EHE

2.2.1 Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredient and the impurities in Dichlorprop-P 2-EHE Technical have been validated and assessed to be acceptable for the determinations.

2.2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

2.2.3 Methods for Residue Analysis

The analytical methods developed for determination of dichlorprop-P, its ethylhexyl ester and their transformation products in soil have been validated and determined to be acceptable for post-registration monitoring methods.

Gas chromatography methods with mass spectrometric detection (GC-MSD; Method AR 258-00 in cereal matrices and Method AR 125-96 in animal matrices) were developed and proposed for data generation and enforcement purposes. These methods fulfilled the requirements with regards to specificity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries (70–120%) were obtained in plant and animal matrices.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

The PMRA conducted a detailed review of the toxicological database for 2,4-DP-P and the ester form of 2,4-DP-P. The database consists of an array of laboratory animal (in vivo) and cell culture (in vitro) toxicity studies currently required for health hazard assessment purposes. The studies were carried out in accordance with currently accepted international testing protocols and Good Laboratory Practices. The scientific quality of the data is acceptable, and the database is considered adequate to characterize the toxicity of these pest control products.

Available toxicity data comparing 2,4-DP-P and the racemic 2,4-DP showed no significant differences in toxicity potential.

There were no data to compare the relative toxicities of 2,4-DP-P and the ester form of 2,4-DP-P (2,4-DP-P EHE). However, the rat metabolism studies on 2,4-DP-P and 2,4-DP-P EHE showed similar pharmacokinetic parameters between these compounds. These studies demonstrated that 2,4-DP-P EHE was readily transformed to the 2,4-DP-P free acid after oral administration, then absorbed, distributed, metabolized, and excreted. Degradation products of 2,4-DP-P include 2,4-dichlorophenol, 2,4-dichloroanisole, and carbon dioxide. An In vitro dissociation/degradation study conducted with 2,4-DP-P EHE showed that all administered 2,4-DP-P EHE was converted to 2,4-DP-P. It was concluded that in the in vivo environment, 2,4-DP-P EHE is expected to hydrolyze to the free acid 2,4-DP-P and any toxicity induced by the ester form would be similar to the acid form. Thus, the toxicity database for the acid can be used to support the registration application of both the acid and ester forms of 2,4-DP-P.

In laboratory animals orally exposed to 2,4-DP-P or 2,4-DP-P EHE, absorption was rapid and extensive. Peak plasma concentrations were seen shortly after exposure. A secondary peak at ~6 h indicated the possibility of entero-hepatic recirculation. The compounds were excreted rapidly in urine with most of the administered radioactivity (AR) collected in urine within 24 h. Fecal elimination constituted about 4-12 % of the AR. A total of 91-97 % of the AR was eliminated within 168 h. No radioactivity was detected in expired air. Total radioactivity remaining in tissues was low, 0.35-1.72% of the AR. After exposure to 2,4-DP-P EHE, the main urinary and fecal metabolite was 2,4-DP-P acid. Minor metabolites totalled to <3 % of the AR. It was concluded that 2,4-DP-P and 2,4-DP-P EHE were absorbed rapidly and extensively, and excreted rapidly in urine, either unchanged or converted to the acid form in the case of 2,4-DP-P EHE. Tissue residues were low with no evidence of accumulation. There were no notable gender differences in the metabolic profile.

Technical 2,4-DP-P and 2,4-DP-P EHE are moderately acutely toxic by the oral route, but are of low acute toxicity by the dermal and inhalation routes of exposure. The acid is extremely irritating to the rabbit eye affecting the cornea, while the eye irritation potential of the ester form of 2,4-DP-P was minimal. The difference in eye irritation potential might be related to the physical form of the acid (solid) and ester (liquid). The solid form of the acid might cause mechanical injury when instilled into the eye. Both the acid and ester forms of 2,4-DP-P were only slightly irritating to the rabbit skin. Although 2,4-DP-P is not a skin sensitizer, the ester is a skin sensitizer when tested in the guinea pig using the maximization method.

Optica Trio, an end-use product containing 2,4-DP-P, is slightly acutely toxic by the oral route, but is of low toxicity by the dermal and inhalation routes of exposure. The formulation is extremely irritating to the rabbit eye, but is only slightly irritating to the rabbit skin. Optica Trio is not a dermal sensitizer when tested in the guinea pig using the maximization protocol.

The end-use product Estaprop XT Liquid Herbicide is moderately acutely toxic by the oral route, but is of low acute toxicity by the dermal and inhalation routes of exposure. The formulations are minimally irritating to the eye or skin, and are not skin sensitizers.

A 28-day dietary toxicity study in the rat using comparable doses of 2,4-DP-P and 2,4-DP racemate demonstrated and verified the similarity of toxic potential. In short- and long-term dietary toxicity studies in mice, rats, and dogs, 2,4-DP-P induced systemic toxicity at high dose levels. Systemic toxicity invariably involved reduced food intake and lowered body weight and body weight gains. The liver and kidneys were the target organs. The effects on these organs included discoloration, pigment deposition, hypertrophy, nephropathy, and evidence of peroxisome proliferation (increased values of cyanide-insensitive palmitoyl-Co-A- oxidation, and the eosinophilic cytoplasm of the hepatocytes and of kidney tubular epithelial cells). Some clinical parameters including enzymes (increased alkaline phosphatase, alanine aminotransferase, bilirubin) associated with these organs were affected. Slight anemia was seen in the rat and the dog. In the dog, diarrhea and ulceration of the gastrointestinal tract (GIT) were evident after dietary exposure to 2,4-DP-P. No signs of selective neurotoxicity were detected in the rat after a single or repeat (90-day) oral administration.

No systemic toxicity was seen after repeated dermal administration of 2,4-DP-P in the rabbit for 21-days or of 2,4-DP-P EHE in the rat for 4 weeks. However, 2,4-DP-P caused erythema, diffuse acanthosis, and diffuse inflammatory cells in the superficial dermis at the application site.

No evidence of mutagenic potential of 2,4-DP-P and of 2,4-DP-P EHE was observed in a battery of in vitro and in vivo genotoxicity assays assessing gene mutation, unscheduled DNA synthesis, and chromosome aberration. 2,-4-DP-P was not carcinogenic when tested in the rat or the mouse after long-term dietary exposure.

A 2-generation dietary study in rats showed 2,4-DP racemic was free of specific, selective effects on reproductive function and fetal development. At the highest dose tested, significant systemic toxicity was observed in parental animals and the pups. Effects on the reproductive function were considered secondary to the systemic toxicity seen. Parental toxicity at this dose level included lower body weights, mild anemia, higher kidney weight, and higher blood cholesterol levels. Reproductive and offspring toxicity occurring at the maternally toxic dose included longer gestation period, increased total litter loss, lower litter size, increased stillbirths, decreased pup care leading to higher pup mortality, lower body weight and body weight gain, and delayed maturation. In order to further demonstrate the similarity of reproductive potential of 2,4-DP-P and 2,4-DP racemate, a supplementary reproductive toxicity study using fewer rats was carried out. The results of the supplementary study verified the findings of the 2-generation reproductive toxicity study with 2,4-DP racemate. There was no evidence of increased sensitivity of the offspring.

Developmental toxicity studies of 2,4-DP-P in rats and rabbits did not demonstrate any teratogenic effects, nor was there evidence of sensitivity of the offspring. At maternally toxic doses, fetal development was delayed as evidenced by the increased incidences of skeletal variation and ossification retardation. Maternal toxicity at higher doses constituted lower food intake and lower body weight. In the rabbit, there was evidence of stomach erosion.

2,4-DP-P was not neurotoxic in acute and 90-day neurotoxicity studies in rats. In the acute neurotoxicity study, 2,4-DP-P induced clinical signs of toxicity at or near lethal dose levels with no evidence for specific neurologic effects. Histopathology revealed no evidence of damage to the nervous system. In the 90-day study, despite clear signs of toxicity such as reduced body weight gain, hematology and liver changes, neither clinical signs nor histopathological evidence of neurotoxic potential was observed. There were no triggers in the toxicological database to warrant a study to investigate developmental neurotoxicity.

In summary, technical 2,4-DP-P is of moderate toxicity by the oral route, of low toxicity by the dermal and inhalation routes, is irritating to the eye and mucous membranes, and is not a dermal sensitizer. Repeated exposures produce liver and kidney toxicity, together with reduced body weight gain. A mild anaemia is seen in some species. 2,4-DP-P and 2,4-DP-P EHE were not genotoxic, carcinogenic, neurotoxic, teratogenic, and did not induce reproductive toxicity at doses that did not cause maternal toxicity.

In conclusion, the toxicological database for 2,4-DP-P and 2,4-DP-P EHE is considered adequate for human risk assessment.

Results of the acute and chronic tests conducted on laboratory animals with 2,4-DP-P and 2,4-DP-P EHE technical and their associated end-use products, along with the toxicology endpoints for use in the human health risk assessment, are summarized in Appendix I Tables 1, 2, and 3.

In assessing the occupational, residential, and dietary risks from potential exposure to 2,4-DP-P and 2,4-DP-P EHE products, the standard uncertainty factor of 100 has been applied to account for interspecies extrapolation and intraspecies variability.

3.1.1 *Pest Control Products Act* Hazard Characterization

For assessing risks from potential residues in food or from products used in or around residential areas or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects. This factor should take into account completeness of the data with respect to the exposure of, and toxicity to, infants and children and potential pre- and post-natal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

With respect to the completeness of the toxicity database, extensive data are available for 2,4-DP-P, 2,4-DP racemate, and 2,4-DP-P EHE, including developmental toxicity studies in rats and rabbits and a reproductive toxicity study in rats.

With respect to identified concerns relevant to the assessment of risk to infants and children, offspring effects identified in the rat reproductive toxicity study (i.e., increased stillbirths, low birth weight, increased total litter loss, decreased litter size and pup care) occurred at a maternally toxic dose. Although the observed effects in the offspring were considered serious endpoints, the concern was tempered by the presence of maternal toxicity. When the NOAEL for the offspring effects is compared with the NOAEL used for human risk assessment, a margin of 6-fold is provided. Thus, the end-point selected provided adequate margins to be protective of the pregnant female, and the *Pest Control Products Act* factor has been reduced to 1-fold.

3.2 Determination of Acute Reference Dose

The assessment of an acute reference dose for 2,4-DP-P is based on the NOAEL of 7 mg/kg bw/d established in the 1-year dog study. Use of this study for ARfD determination is relevant because diarrhea occurred in dogs at the LOAEL of 22 mg/kg bw/d within one week of dietary exposure. The standard uncertainty factors (10-fold for interspecies extrapolation and 10-fold for intraspecies variability) have been applied. As discussed in the previous section, the *Pest Control Products Act* factor has been reduced to 1-fold. The composite assessment factor (CCAF) is 100.

The ARfD proposed is calculated according to the following formula:

$$\text{ARfD} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{7\text{ mg/kg bw/d}}{100} = 0.07\text{ mg/kg bw}$$

3.3 Determination of Acceptable Daily Intake

The most relevant NOAEL established for ADI determination was derived from the 18-month dietary oncogenicity study in the mouse. At the LOAEL of 64 mg/kg bw/d, chronic nephropathy was evident. The NOAEL was 6.8 mg/kg bw/d. Use of this end-point is considered protective of all sub-populations. The standard uncertainty factors (10-fold for interspecies extrapolation and 10-fold for intraspecies variability) have been applied. As discussed in the previous section, the *Pest Control Products Act* factor has been reduced to 1-fold. The composite assessment factor is 100.

The ADI proposed is calculated according to the following formula:

$$\text{ADI} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{6.8 \text{ mg/kg bw/d}}{100} = 0.07 \text{ mg/kg bw/d}$$

3.4 Occupational and Residential Risk Assessment

3.4.1 Toxicological Endpoints

Short-term to intermediate-term dermal

Available dermal toxicity studies consist of a 21-day study with 2,4-DP-P in the rabbit and a 4-week study using 2,4-DP-P EHE in the rat. These are adequate and valid studies. Both studies supported a NOAEL of 1000 mg/kg bw/d, the highest dose tested. Use of this end-point is considered protective of all sub-populations, including nursing infants and unborn children of exposed female workers. The standard uncertainty factors (10-fold for interspecies extrapolation and 10-fold for intraspecies variability) applied provide a target margin of exposure (MOE) of 100.

Short-term to intermediate-term inhalation

No repeat-dose inhalation toxicity studies were available for 2,4-DP-P or 2,4-DP-P EHE. For short-term and intermediate-term inhalation exposures, the NOAEL of 7 mg/kg bw/d established in the 1-year dietary dog toxicity study is deemed appropriate for irritation of mucous membranes. Use of this end-point is considered protective of all sub-populations, including nursing infants and unborn children of exposed female workers. The standard uncertainty factors (10-fold for interspecies extrapolation and 10-fold for intraspecies variability) applied provide a target margin of exposure of 100.

3.4.2 Occupational and Residential Risk Assessment

3.4.2.1 Dermal Absorption

As toxicology endpoints from the dermal toxicity study were used for occupational exposure and risk assessment, an estimate of dermal absorption was not required. Therefore, the available chemical specific dermal absorption study was not reviewed.

3.4.2.2 Occupational Exposure and Risk

3.4.2.2.1 Mixer/loader/applicator (M/L/A) Exposure and Risk Assessment

Farmers, commercial applicators, aerial mixer/loaders and aerial applicators have potential for exposure to 2, 4-DP-P, by the dermal and inhalation routes. Exposure would occur during mixing, loading and applying by a ground or an aerial method. No 2,4-DP-P-specific mixer/loader/applicator exposure data were submitted by the applicant. Therefore, the M/L/A daily exposures were quantified using a Tier 1 risk assessment approach by coupling the dermal or inhalation generic unit exposure data from the Pesticide Handlers Exposure Database (PHED) Version 1.1., with the amount of product handled per day and 100% dermal or 100% inhalation absorption values. Exposure was normalized to mg/kg bw/day by using 70 kg adult body weight. The estimated daily exposures were compared to the toxicological endpoints to obtain MOEs. The MOEs for all M/L/A exposure scenarios of 2,4-DP-P were above the target of 100 and acceptable (Appendix I, Table 15).

3.4.2.2.2 Postapplication Exposure and Risk Assessment for Workers Entering Treated Areas

The postapplication exposure potential to workers entering 2,4-DP-P treated fields is low as harvesting of cereal crops is by mechanical methods. The low exposure could occur to re-entry workers scouting, irrigating and assessing the efficacy of the product. Significant re-entry activities are not expected in the treated industrial and non-crop land areas, except for scouting. Potential re-entry exposure would be for a short- to intermediate-term, primarily by the dermal route. Based on the very low vapor pressure of 2,4-DP-P, application of formulation in water and further dilution in the outdoor air, the potential for inhalation exposure is expected to be negligible. Therefore, further assessment of the postapplication inhalation exposure was not conducted. No 2,4-DP-P specific dislodgeable foliar residue (DFR) dissipation study was submitted. Therefore, the exposure of a postapplication worker to 2,4-DP-P treated plants/trees was generated by a Tier 1 approach for foliage treatment by coupling default DFR values with the activity specific transfer coefficients (TCs) for scouting and irrigation and the 8 hour duration of a work day. Default values for body weight (70 kg) and 100 % default dermal absorption were used. The estimated exposure was compared to the toxicological endpoint to obtain the MOE. The postapplication exposure and risk estimates on the day of application are presented in Appendix I Table 16.

The MOEs for all postapplication exposure scenarios of 2,4-DP-P were above the target of 100 and acceptable. No risk-based re-entry interval is required. However, a default restricted entry interval (REI) of 12 hrs was recommended to allow for residues to dry before reentering a treated field (Appendix I Table 16).

3.4.3 Residential Exposure and Risk Assessment

No residential uses were requested for registration.

3.4.4 Bystander Exposure and Risk

No significant bystander exposure is expected as the uses are limited to agricultural crops and industrial non-cropland areas. In addition, the product application directions on the labels include statements to minimize spray drift. Therefore, the bystander exposure and risk are considered negligible.

3.5 Food Residues Exposure Assessment

3.5.1 Concentrations in Drinking Water

Estimated environmental concentrations (EECs) of dichlorprop-P in potential drinking water sources (groundwater and surface water) were estimated using computer simulation models. An overview of how the EECs are estimated is provided in the PMRA's Science Policy Notice SPN2004-01, *Estimating the Water Component of a Dietary Exposure Assessment*. EECs of dichlorprop-P in groundwater were calculated using the LEACHM model to simulate leaching through a layered soil profile over a 50-year period. The concentrations calculated using LEACHM are based on the flux, or movement, of pesticide into shallow groundwater with time. EECs of dichlorprop-P in surface water were calculated using the PRZM/EXAMS models, which simulate pesticide runoff from a treated field into an adjacent water body and the fate of a pesticide within that water body. Pesticide concentrations in surface water were estimated in two types of vulnerable drinking water sources, a small reservoir and a prairie dugout.

A Level 1 drinking water assessment was conducted using conservative assumptions with respect to environmental fate, application rate and timing, and geographic scenario. The Level 1 EEC estimate is expected to allow for future use expansion into other crops at this application rate. Table 3.5.1.1 lists the application information and main environmental fate characteristics used in the simulations. Ten initial application dates between April and July were modelled. The model was run for 50 years for all scenarios. The largest EECs of all selected runs are reported in Table 3.5.1.2.

Table 3.5.1.1 Major groundwater and surface water model inputs for Level 1 assessment of dichlorprop-P

Type of Input	Parameter	Value
Application Information	Crop(s) to be treated	barley, oats, brush control, and roadside weed control.
	Maximum allowable application rate per year (g a.i./ha)	1500
	Maximum rate each application (g a.i./ha)	1500
	Maximum number of applications per year	1
	Minimum interval between applications (days)	N/A
	Method of application	Ground/aerial
Environmental Fate Characteristics	Hydrolysis half-life at pH 7 (days)	stable
	Photolysis half-life in water (days)	11
	Adsorption K_{OC} (mL/g)	46.06 (20th percentile of K_{OC} values for dichlorprop-P)
	Aerobic soil biotransformation half-life (days)	16.1 (80th percentile of four half-life values)
	Aerobic aquatic biotransformation half-life (days)	15 (longest of two half-lives)
	Anaerobic aquatic biotransformation half-life (days)	474

Table 3.5.1.2 Level 1 estimated environmental concentrations of dichlorprop-P in potential drinking water

Crop	Groundwater (µg a.i./L)		Surface Water (µg a.i./L)			
			Reservoir		Dugout	
	Daily[1]	Yearly[2]	Daily[3]	Yearly[4]	Daily[3]	Yearly[3]
wheat	31	31	118	10.0	64	7.8

Notes:
1 90th percentile of daily average concentrations
2 90th percentile of yearly average concentrations
3 90th percentile of yearly peak concentrations
4 90th percentile of yearly average concentrations

Details of water modelling inputs and calculations are available upon request.

A search for water monitoring data on dichlorprop in Canada resulted in a number of samples with detections being reported. A request was sent to the Federal, Provincial and Territorial representatives from all of the provinces and territories in Canada, requesting water monitoring data. In addition, requests were submitted to Environment Canada, the Department of Fisheries and Oceans and the Federal, Provincial and Territorial Committee on drinking water through Health Canada. US databases were also searched for detections of dichlorprop. Data on residues present in water samples taken in the US are important to consider in the Canadian water assessment given the extensive monitoring programs that exist in the US. Runoff events, local use patterns, circumstantial hydrogeology as well as testing and reporting methods are probably more important influences on residue data rather than Northern versus Southern climate. As for the climate, if temperatures are cooler, residues may break down more slowly, on the other hand if temperatures are warmer, growing seasons may be longer and inputs may be more numerous and frequent.

Data from Canadian and US water monitoring studies in which dichlorprop was quantified are summarized in Appendix III, Table 1. For purposes of the drinking water assessment, information was extracted from the available sources, tabulated and sorted into categories as follows:

> Residues in known drinking water sources (both surface and groundwater)
> Residues in ambient water that may serve as a drinking water source (both surface and groundwater)
> Residues in ambient water unlikely to serve as a drinking water source

An important limitation of the monitoring data set is that, in many cases, the data were not accompanied with use data for dichlorprop. For instance, the application rate applied, when the application occurred and weather conditions prior to sampling were not known or reported. Without this information, it is difficult to conclude if non-detects were a result of non-transport or more simply a result of inappropriate timing of sampling. In addition, because the data are sparse and concentrations vary in time and space, the maximum concentration reported is unlikely to be the absolute maximum concentration that would be observed in Canada. Factors that may result in higher concentrations being detected include application at higher rates, precipitation and some areas/soils are simply more prone to leaching and/or run off. Sampling at intervals immediately following application would increase the likelihood that the maximum concentration would be detected.

Thus, it is likely dichlorprop was not used in some of the areas monitored, and that higher concentrations of dichlorprop may occur in other areas not monitored. The dichlorprop monitoring data likely underestimate the peak exposure because of the following limitations:

1. In general, the data are sparse in both time and location. In some of the studies available, dichlorprop was analyzed in samples that were taken from non-dichlorprop use areas. Dichlorprop use information from the areas surrounding where the samples were collected is often not available.

2. Sampling in some of the studies was conducted during periods when dichlorprop is not applied in Canada (i.e., October through March).

3. The concentrations of chlorophenoxy pesticides in surface water are directly related to the frequency and timing of monitoring in relation to pesticide application and runoff events. Therefore, timing and frequency of sampling is likely to be the most important factor influencing the concentration detected and the frequency of detections. Samples are often taken at arbitrary time intervals (i.e., once a month, once a week) and are unlikely to capture the absolute maximum concentration of dichlorprop-P.

The detection frequency provides an indication of how often positive detections occur within the given data set. Detection frequency is primarily determined by the limits of detection and is influenced by pesticide use patterns and application rates. Consequently, a wide range of detection frequencies is likely to be expected (Appendix III Table 1).

3.5.2 Residues in Plant and Animal Foodstuffs

The residue definition for risk assessment and enforcement in plant products and animal commodities is dichlorprop. The GC-MS enforcement methods are valid for the quantification of dichlorprop or dichlorprop-P residues (the method cannot differentiate between isomers) in cereal grains and livestock matrices. The residues of dichlorprop-P are stable when stored in a freezer at -20°C for 10 months in grass and 18 months in barley green plant, straw and grain. Cereal processing data were not required due to the lack of quantifiable residues in grain treated at a five-fold exaggerated rate. The requirement for magnitude of residues in livestock matrices was waived. Supervised residue trials conducted throughout Canada using end-use products containing dichlorprop-P at the approved rates in or on wheat, barley and field corn are sufficient to support the proposed maximum residue limits.

3.5.3 Dietary Risk Assessment

Acute and chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM–FCID™, Version 2.16), which uses updated food consumption data from the United States Department of Agriculture's Continuing Surveys of Food Intakes by Individuals, 1994–1996 and 1998.

3.5.3.1 Chronic Dietary Exposure Results and Characterization

The following assumptions were made in the basic chronic analysis: 100% crop treated, residues in wheat, barley and oats, and animal commodities at the MRL level. The basic chronic dietary exposure from all supported dichlorprop-P food uses (alone) for the total population, including infants and children, and all representative population subgroups are ≤0.8% of the acceptable daily intake (ADI). Aggregate exposure from food and water is considered acceptable. The PMRA estimates that chronic dietary exposure to dichlorprop-P from food and water is 1.2% of the ADI for the total population. The highest exposure and risk estimate is for all infants (<1 year) old at 3.3% of the ADI.

3.5.3.2 Acute Dietary Exposure Results and Characterization

The following assumptions were made in the basic acute analysis: 100% crop treated, residues in wheat, barley and oats, and animal commodities at the MRL level. The basic acute dietary exposure (food alone) for all supported dichlorprop-P registered commodities is estimated to be ≤1.7% of the ARfD for the general population (95th percentile, deterministic). Aggregate exposure from food and water is considered acceptable: ≤14.7% of the ARfD for the general population.

3.5.4 Aggregate Exposure and Risk

The aggregate risk for dichlorprop-P consists of exposure from food and drinking water sources only; there are no residential uses. Aggregate risks were calculated based on acute and chronic endpoints.

3.5.5 Maximum Residue Limits

Table 3.5.5.1 Proposed Maximum Residue Limits

Commodity	Recommended MRL
Crop group 15 (Cereal grain)	0.02 ppm
Milk	0.01 ppm
Eggs; Fat and Meat of cattle, goats, hogs, horses, poultry and sheep	0.02 ppm
Meat by-products of cattle, goats, hogs, horses, poultry and sheep	0.05 ppm

For additional information on Maximum Residue Limits (MRL) in terms of the international situation and trade implications, refer to Appendix II.

The nature of the residues in animal and plant matrices, analytical methodology, field trial data, and the acute and chronic dietary risk estimates are summarized in Appendix I Tables 1, 4 and 5.

4.0 Impact on the Environment

Due to the rapid hydrolysis of 2,4-DP-P EHE (< 1 hour) under most environmental conditions to the 2,4-DP-p acid, the PMRA employed an environmental fate bridging strategy for 2,4-DP-p EHE. The environmental fate bridging strategy focused the exposure assessment on 2,4-DP-p acid except for the special circumstance of direct deposition of 2,4-DP-p EHE into aquatic environments from spray drift. Based on abiotic hydrolysis data, 2,4-DP-p EHE may persist in waters with an acidic or neutral pH. However, 2,4-DP-p EHE is not expected to persist in runoff waters due to microbial-mediated hydrolysis or surface catalyzed hydrolysis in soil:water slurries. Therefore, 2,4-DP-p EHE exposure to aquatic environments is most likely to occur through spray drift.

2,4-DP-p acid enters the terresterial environment when it is used as a herbicide on wheat, barley, non-cropland and brush control. 2,4-DP-p acid is a weak organic acid, it is very soluble in water and is considered non-volatile according to the USEPA classification (1975). Although phototransformation of 2,4-DP-p acid on soil does take place it is expected to be a secondary route of transformation. Volatilization and subsequent phototransformation of 2,4-DP-p acid in air is unlikely due to its low vapour pressure and Henry's law constant. Aerobic biotransformation is an important route of transformation for 2,4-DP-p acid. Minor transformation products of 2,4-DP-p are 2,4-dichlorophenol and 2,4-dichloroanisole, although it is suspected that some of the 2,4-dichlorophenol is present as an impurity from the synthesis from 2,4-dichlorprop-P (up to 0.5%) and its presence may not be entirely due to biotic processes. Under Canadian field conditions, 2,4-DP-p acid is non-persistent.

2,4-DP-p is mobile in the soil, has potential to leach to groundwater and in some circumstances may flow into surface water. Field studies indicate that 2,4-DP-p acid can reach soil depths of 61 cm. As a result of this behaviour, 2,4-DP-p acid is not expected to be transported to the aquatic environment via soil particles during runoff events. 2,4-DP-p is mobile in soil, has potential to leach to groundwater and in some circumstances may eventually flow into surface water.

2,4-DP-p acid is expected to remain in the water column as it has a low K_{oc} and is very water soluble. 2,4-DP-p acid appears to be non-persistent under aerobic conditions, and moderately persistent under anaerobic conditions. 2,4-DP-p acid can enter aquatic environments through spray drift from the application site. 2,4-DP-p acid is very soluble in water, and appears to be stable to hydrolysis. Phototransformation and biotransformation of 2,4-DP-p acid are important routes of transformation in the aquatic environment. No major transformation products of 2,4-DP-p acid in terrestrial and aquatic environments were observed.

Data on the fate and behaviour of 2,4-DP-p acid and its transformation products are summarized in Appendix I Table 7. The structure and the percent detected of the major and minor transformation products of 2,4-DP-p acid are presented in Appendix I Table 9.

4.1 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental exposure concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (i.e. protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC = 1). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

4.1.1 Risks to Terrestrial Organisms

Risks of 2,4-DP-p acid and its related end-use products to terrestrial organisms were based upon the use pattern for the end-use products and the evaluation of toxicity data for the following surrogate species (Appendix I Table 10):

- One earthworm species, one bee species, two other arthropods representing invertebrates
- Two bird and one mammal species representing vertebrates
- 10 crop species representing vascular plants

The screening level RQs for Estaprop XT Liquid Herbicide were assessed based on the maximum application rate for a single application of 2520 g a.i./ha for earthworms, honeybees, predators and parasites, birds, small mammals and terrestrial plants as these organisms may be exposed through direct application, contact with treated material or from ingestion of contaminated food.

Terrestrial Invertebrates

Risk quotients calculated for the screening level risk assessment did not excced the level of concern. The use of 2,4-DP-p acid is not expected to pose a risk to earthwormsor honey bees and although it was expected to pose a risk to other non-target arthropods on-field, the off-field risk was below the level of concern.

The acute LC_{50} value for 2,4-DP-p acid to earthworms was > 1000 mg a.i./kg soil, representing the highest concentration tested. The RQ calculated (Appendix I Table 12) did not exceed the level of concern.

The acute contact and acute oral LD_{50} values for 2,4-DP-p EHE were > 178 µg a.i./bee and > 180 µg a.i./bee, respectively. Both of these represent the highest dose tested with no subacute effects noted at any concentration tested. The LD_{50} in micrograms per bee (µg/bee) can be converted to the equivalent application rate in kg/ha by multiplying µg/bee by 1.12. After conversion, the acute oral LD_{50} value was 202 kg a.i./ha and the acute contact LD_{50} value was 199 kg a.i./ha. An RQ was calculated using the following equation: LD_{50}/EEC; where the EEC is the proposed maximum seasonal application rate of 2520 g a.i./ha. The RQs calculated and presented in Table 12 Appendix I do not exceed the level of concern. The use of 2,4-DP-p acid is not expected to pose an acute risk on a contact or oral basis to bees. The contact LD_{50} values for 2,4-DP-p EHE were 261 g a.i./ha and 521 g a.i./ha for predatory and parasitic species, respectively. There is an on-field risk for predatory and parasitic arthropods at the highest proposed application rate of 2,4-DP-p acid for non-cropland and brush control uses, however, risk is below the level of concern for the off-field exposure scenario.

Terrestrial Vertebrates

Toxicity to Birds

Available acute toxicity data indicate that 2,4-DP-p EHE and 2,4-DP-p DMA are moderately toxic to bobwhite quail in oral gavage studies. However, acute dietary studies with bobwhite quail and mallard duck indicate that 2,4-DP-p EHE and 2,4-DP-p DMA were practically non-toxic. One chronic reproductive dietary study with Japanese quail indicated 2,4-DP-p DMA was toxic to Japanese quail based on an NOAEC of 245 mg a.e./kg . This study was based on the 2,4-DP-p DMA 600 formulation (AH Marks Dichloroprop-P DMA 600; USEPA registration number 15540-30). This formulated product contains 65% a.i. and is used to produce an end-use product.

Toxicity to Mammals

Toxicity data for mammals indicated that 2,4-DP-p acid is slightly toxic to rats (Appendix I Table 10) on an acute basis based on an endpoint of 567 mg a.i./kg bw for both male and female rats. The most sensitive chronic endpoint was from the chronic two-generation reproductive study with rats with a NOAEL of 40 and 42 mg a.i./kg/bw/day for male and female rats, respectively.

Toxicity endpoints were converted into daily doses with food ingestion rates and body weight using default values for the bird and mammalian assessments (Appendix I Table 13). These values were then compared to the daily exposure estimates to calculate the risk quotients. The exposure estimates for birds are calculated based on the body weight of the organisms and the amount and type of food consumed.

Since Estaprop XT Liquid Herbicide and Optica Trio are to be applied once per year, the EECs were based on residues immediately following one application at the maximum rate of 2520 g a.i./ha (brush control) for the screening level assessment. Since exposure is dependent on the body weight of the organisms and the amount and type of food consumed, the screening level risk assessment considers a set of generic body weights (20, 100, 1000 g for birds and 15, 35, 1000 g for mammals) and food preferences (100% small insects for insectivores, 100% fruits for frugivores, 100% grain and seeds for granivores and 100% leaves and leafy crop for herbivores) considered at the screening level provide the most conservative EEC for each food guild. Additionally, the acute toxicity endpoint is divided by an uncertainty factor of 10 to account for potential differences in species sensitivity as well as varying protection levels (for example, community, population, and individual).

Risk to Birds

In a refined assessment (Appendix I Table 13), the mean residues were considered to provide a more realistic assessment of the potential risks to birds. Pesticide specific foliar dissipation data were not available for 2,4-DP-p acid. This assessment showed risk quotients to be below the level of concern when mean residue values were assumed except for small and medium frugivorous insectivorous birds where the level of concern was exceeded slightly. For the level of concern to be reached, 100% of their diet would have to consist of contaminated food preferences at the mean residue levels. As this is an acute risk, it is unlikely that enough insects or fruits are likely to be consumed in significant quantities in a single day or single feeding session. In the case of insectivores, considering the mobility of insects and the birds, this is not considered a realistic exposure pattern.

The leaves and foliage category can, however, be removed from the risk assessment and it is relevant to do so in this case as the EPs for dichlorprop-P are not used on leafy crops (for example, lettuce) nor is it relevant for the off-field assessment since lettuce-type foliage is less typical in wild plant populations.

Risk to Mammals

In a refined assessment (Appendix I Table 13), the mean residues were considered to provide a more realistic assessment of the potential risks to mammals. Pesticide specific foliar dissipation data were not available for 2,4-DP-p acid. This assessment showed risk quotients to be below the level of concern when mean residue values were assumed except for medium herbivorous mammals where the level of concern was exceeded slightly. For the level of concern to be reached, 100% of their diet would have to consist of contaminated food preferences at the mean residue levels. Feeding exclusively on grasses and forage crops by herbivorous mammals is not considered a realistic scenario as the highest application rate is used for brush control, where grasses form a small portion of the plant material.

Because herbivorous mammals may feed on forage crops, the next highest application rate of 1500 g a.i./ha (wheat and barley) was assessed in a further refinement (Appendix I Table 13). In this refined assessment the application rates, mean residues and foraging behaviour of the non-target animals are considered to provide a more realistic assessment of the potential risks to mammals. The lower application rate of 1500 g a.i./ha for crops and using mean residues did not result in an exceedance of the level of concern for medium sized herbivorous mammals foraging on crops.

Plants

Terrestrial plant toxicity studies indicate that 2,4-DP-p acid, 2,4-DP-p DMA and 2,4- DP-p EHE negatively impact seedling emergence and vegetative vigor in monocots and dicots. Consequently, exposure to 2,4-DP-p presents a potential risk to non-target plants inhabiting edge habitats adjacent to spray areas and riparian vegetation along streams and/or ponds in close proximity to sprayed areas. Terrestrial buffer zones were calculated with consideration of the actives used as co-formulants in the various end-use products and based upon the maximum seasonal application rates for each product. End-use products that are comprised of co-formulants can exhibit different toxicity profiles than end-use products formulated with a single active ingredient.

4.1.2 Risks to Aquatic Organisms

The environmental fate bridging strategy focused the exposure assessment on 2,4-DP-p acid except for the special circumstance such as direct deposition of 2,4-DP-p EHE into aquatic environments from spray drift. Based on abiotic hydrolysis data, 2,4-DP-p EHE may persist in waters with an acidic or neutral pH. However, 2,4-DP-p EHE is not expected to persist in runoff waters due to microbial-mediated hydrolysis or surface catalyzed hydrolysis in soil:water slurries. Therefore, 2,4-DP-p EHE exposure to aquatic environments is most likely to occur through spray drift.

Aquatic organisms can be exposed to 2,4-DP-p as a result of drift and runoff from the application of the various end-use products. To assess the potential effects from exposure to 2,4-DP-p, the screening level EECs in the aquatic environment were based on direct application to water at the maximum seasonal rate for brush control (2520 g a.i./ha). The calculated EECs were those determined in a 15 cm body of water for amphibians and an 80 cm body of water for all other aquatic organisms. For the screening level risk assessment for aquatic organisms the laboratory endpoints were adjusted using uncertainty factors to account for differences in species sensitivity and protection goals (for example, community, population and individual). The screening level assessments did not result in the level of concern (LOC) being exceeded, and so a refined assessment was not required (Appendix I Table 14). A risk assessment considering runoff was not considered as there was no risk found using the screening level or most conservative scenario which assumes direct overspray of a water body at the maximum application rate for brush control.

Risks of 2,4-DP-p acid and its related end-use products to aquatic organisms were based upon the use pattern for the end-use products and the evaluation of toxicity data for the following surrogate species (Appendix I Table 11):

- One invertebrate species (acute and long-term exposure)
- One fish species
- Amphibian species using the fish toxicity studies as surrogate
- One green algae, one blue-green algae, one diatom and one freshwater vascular plant species
- One marine diatom species

Available acute toxicity data indicate that 2,4-DP-p acid was practically non-toxic to rainbow trout and daphnid. No toxicity studies have been conducted to determine potential chronic effects to freshwater fish. Chronic toxicity study for aquatic invertebrates showed no effects at the highest concentration tested. No toxicity studies have been conducted to determine potential acute and chronic effects to estuarine marine fish and aquatic invertebrates. In the 96 hour toxicity study for marine diatoms (*Skeletonema costatum*) performed with 2,4-DP-p DMA, reductions in cell density, area under the curve, and growth rate were noted. Laboratory studies indicate that 2,4-DP-p acid is toxic to aquatic non-vascular and vascular plant species, based on observed adverse effects on growth and development.

Aquatic Invertebrates – Freshwater and Marine

The acute toxicity studies with 2,4-DP-p using daphnids showed no mortality/immobility during a 48 hour acute toxicity test that provided an EC_{50} of >88 mg a.i./L. No reproductive effects on daphnids were noted for 2,4-DP-p with a NOEC of 103 mg a.i./L (reproduction and survivability). There were no toxicity data provided for marine invertebrates.

Fish – Freshwater

Acute toxicity studies with 2,4-DP-p were submitted for one freshwater fish species. The acute toxicity study with 2,4-DP-p using rainbow trout showed no mortality during the 96 hour acute toxicity study with an EC_{50} value of >216 mg a.i./L.. Calculated risk quotients for freshwater fish indicate that the LOC for acute effects was not exceeded (Appendix I Table 14).

Amphibians

No studies assessing the toxicity of 2,4-DP-p to amphibians were submitted. In order to assess the risk to amphibians resulting from an acute and a chronic exposure to 2,4-DP-p, the endpoint values for fish were used as surrogate data, along with the EEC in a 15-cm deep body of water. The acute toxicity study with 2,4-DP-p using rainbow trout provided a 96-h EC_{50} mortality estimate of 21.6 mg a.i./L. No chronic data for fish were provided so chronic endpoints for amphibians could not be estimated. Calculated risk quotients for amphibians indicate that the LOC for acute effects was not exceeded (Appendix I Table 14).

Aquatic Plants

Acute studies of freshwater algae and vascular plant exposure to 2,4-DP-p were submitted. The most sensitive endpoints determined for acute exposure were EC_{50}: 10 mg a.i./L and 16 mg a.i./L for 2,4-DP-p to algae and vascular plants, respectively.

The acute toxicity test for marine diatoms showed effects on growth rate and reductions in cell density. The 72 and 96 hour EC_{50} values based on cell density were 261 and 249 mg a.e./L, respectively. Calculated risk quotients for both freshwater and marine invertebrates demonstrate that the LOC for acute effects was not exceeded (Appendix I Table 14).

The calculated risk quotients indicate that the RQs for acute exposure of aquatic plants do not exceed the LOC (Appendix I Table 14).

Data Gaps for Aquatic Organisms

As per the relevant USEPA RED (EPA-HQ-OPP-2006-0944-0016[1]), the USEPA identified gaps in the effects dataset for 2,4-DP-p acid and 2.4-DDP-P EHE. These datagaps prevented the establishment of definitive effects measurement endpoints for the following taxonomic groups for 2,4-DP-p acid and 2,4-DP-p EHE: chronic freshwater fish, chronic freshwater invertebrates, acute estuarine marine fish, chronic estuarine marine fish, acute estuarine marine invertebrates, and chronic estuarine invertebrates. Therefore, the USEPA calculated estimates for measurement endpoints for these taxonomic groups by evaluating the available data for other phenoxy herbicides and conservatively extrapolating the findings to available data for 2,4-DP-p acid, and

EHE to estimate possible effects measurement endpoints. The USEPA then compared estimated environmental concentrations for surface waters with these endpoints. In all cases, the USEPA concluded that resulting estimated risk quotients, had they been based on definitive effects measurement endpoints, would not trigger concerns for acute or chronic risks to these taxonomic groups. In fact, the RQ estimates were multiple orders of magnitude below the USEPA LOCs. Estimates of risks based on these extrapolated effects measurement endpoints are uncertain and therefore were not considered by the USEPA to be complete substitutes for missing effects data. However, given the conservative methods employed in their derivation, and the high degree to which resulting RQ estimates are below the USEPA concern levels, the USEPA considered it highly unlikely that endpoints developed using test data with 2,4-DP-p would significantly alter the RQ estimates or alter the conclusions of the risk assessment for these taxonomic groups. The exposures calculated by the USEPA were based upon an application rate of 6 lbs. a.i./acre or 6725 g a.i./ha. The maximum application rate for Canadian registration is 2520 g a.i./ha or 2.6 times less than the maximum application rate in the United States. As such, it was expected that the resulting risk quotients from the lower Canadian application rate would be correspondingly lower than those calculated by the USEPA. This approach, akin to a "read-across QSAR", was adopted by the PMRA as reasonable. The data gaps for the PMRA 2,4-DP-p EHE database are similar to those noted in the USEPA RED. Considering that dichloroprop (racemic form) has been in use for about 30 years without any incident reports on marine organisms, that it is non-toxic to freshwater fish and invertebrates, and that exposure to marine organisms is expected to be limited, these data will not be requested. Significant expansions to the use pattern that would result in increased exposure to marine organisms would require the PMRA to revisit this decision.

Aquatic buffer zones were calculated with consideration of the actives used as co-formulants in the various end-use products and based upon the maximum seasonal application rates for each product. End-use products that are comprised of co-formulants can exhibit different toxicity profiles than end-use products formulated with a single active ingredient.

4.1.3 Environmental Incident Reports

Dichlorprop (racemic form, registration number 20450) has been registered for use as herbicide for more than 30 years.

No incident reports were found for dichlorprop-P as of February 3, 2010.

5.0 Value

5.1 Effectiveness Against Pests

Estaprop XT Liquid Herbicide:

Efficacy data were submitted from 24 replicated field trials conducted over a 2-year period at several locations in Alberta, Saskatchewan, and Manitoba. All trials were conducted in cereal crops where Estaprop XT Liquid Herbicide was applied at a rate of 0.73 kg a.i./ha (1.2 L/ha). In all trials Estaprop XT Liquid Herbicide was applied side-by-side with Estaprop Liquid Herbicide (registration number 14803), containing dichlorprop and 2,4-D ester, applied at the registered rate. The herbicide treatments were applied using small plot application equipment. Data were provided for 13 weed species listed on the Estaprop XT Liquid Herbicide label. The efficacy of Estaprop XT Liquid Herbicide was visually assessed as percent weed control and compared to an untreated weedy check or a grass-free check. Observations were made on one or two occasions throughout the growing season.

A scientific rationale was provided in support of weed claims in non-crop areas and for brush control.

Optica Trio:

Efficacy data were submitted from 92 replicated field trials conducted over a 2-year period at several locations in Alberta, Saskatchewan, Manitoba, Ontario, Québec and Prince Edward Island. All trials were conducted in cereal crops where Optica Trio was applied at rates ranging from 450 g a.i./ha to 1500 g a.i./ha in the field trials designed to assess the efficacy at various rates. The herbicide treatments were applied using small plot application equipment. Data were provided for all weed species listed on the Optica Trio label. The efficacy of Optica Trio was visually assessed as percent weed control and compared to an untreated weedy check. Observations were made up to four times throughout the growing season

Acceptable Efficacy Claims

Estaprop XT Liquid Herbicide Applied as a Stand-Alone Herbicide Treatment

The submitted efficacy data and scientific rationale support the claim that Estaprop Liquid Herbicide (registration number 14803), Estaprop Plus Liquid Herbicide (registration number 27968) and Estaprop XT Liquid Herbicide (registration number 29660) are agronomically equivalent. Therefore, the weed control claims summarized in Table 5.1.1 below for Estaprop XT Liquid Herbicide applied alone are supported.

Table 5.1.1 Weed Control Claims for Estaprop XT Liquid Herbicide

Use-Site	Herbicide Rate	Weeds Controlled
Cereal Crops	0.73 kg a.i./ha or 1.2 L/ha	annual sow-thistle, ball mustard, blue bur, burdock, Canada thistle (top-growth only), cocklebur, curled dock (top-growth only), dog mustard, flixweed, hare's ear mustard, Indian mustard, kochia, lady's-thumb, lamb's-quarters, night-flowering catchfly, oak-leaved goosefoot, perennial sow-thistle (top-growth only), ragweed, redroot pigweed, round-leaved mallow, Russian pigweed, Russian thistle, shepherd's purse, smartweed, stinkweed, stork's-bill, tartary buckwheat, tumble mustard, volunteer rapeseed (canola), volunteer sunflower, wild buckwheat, wild mustard, wormseed mustard, and toadflax (suppression)
Industrial and non-crop uses	1.7 kg a.i./ha or 2.8 L/ha	alfalfa, bull thistle, burdock, buttercup, Canada thistle, chicory, cinquefoil, curled dock, dandelion, dogbane, goat's-beard, goldenrod, hawkweed, horsetail (partial control), milkweed (topkill), mullein, plantain, perennial sow-thistle, sweet clover, tansy, teasel, toadflax, vetch, wild carrot, and yellow rocket
Brush control - low rate	2.7-5.5 kg a.i./ha or 4.5-9 L/ha	buckbrush, hawthorn, poplar, scotch pine, sugar maple, white cedar, wild cherry, wild plum, and wild raspberry
Brush control - high rate	3.7-7.3 kg a.i./ha or 6-12 L/ha	alder, aspen, basswood, balsam fir, birch, bur oak, blueberry, elderberry, elm, ground juniper, hardhack, hazel, hickory, honeysuckle, Manitoba maple, poison ivy, raspberry, red pine, rose (some regrowth), silver maple, sugar maple (some regrowth), sumac, tamarack, white oak, wild apple, and willow

Optica Trio Applied as a Stand-Alone Herbicide Treatment

The submitted efficacy data support the weed control claims summarized in Table 5.1.2 for Optica Trio applied alone.

Table 5.1.2 Weed Control and Suppression Claims for Optica Trio

Herbicide Rate	Weeds Controlled	Weeds Suppressed
900 g a.i./ha or 1.5 L/ha	stinkweed, wild mustard, lamb's-quarters, volunteer canola	
1500 g a.i./ha or 2.5 L/ha	common chickweed, wild buckwheat, redroot pigweed, kochia, common ragweed, cleavers[1]	lady's thumb Canada thistle (top growth suppression)

[1] Cleavers: Spray in 1-2 whorl stage

Herbicide Tank Mix Combinations

The weed control claims summarized in Table 5.1.3 for Estaprop XT Liquid Herbicide applied in tank mix are supported.

Table 5.1.3 Weed Claims for Estaprop XT Liquid Herbicide Applied in Tank-Mix

Herbicide	Rate	Weeds Controlled or Suppressed
Estaprop XT Liquid Herbicide + Achieve Liquid Herbicide + Turbocharge or Turbocharge Est	**0.73 kg a.i./ha** (1.2 L/ha) **+ 0.2 kg a.i./ha** (0.5 L/ha) **+ 0.5%v/v**	broadleaf weeds controlled or suppressed by Estaprop XT Liquid Herbicide alone at the same rate + grass weeds controlled by Achieve Liquid Herbicide + Turbocharge at the same rate
Estaprop XT Liquid Herbicide + Assert 300 SC Herbicide	**0.73 kg a.i./ha** (1.2 L/ha) **+ 0.39 kg a.i./ha** (1.3 L/ha) **to 0.48 kg a.i./ha** (1.6L/ha)	broadleaf weeds controlled or suppressed by Estaprop XT Liquid Herbicide alone at the same rate + weeds controlled or suppressed by Assert 300 SC Herbicide at the same rate
Estaprop XT Liquid Herbicide + Avenge 200-C Wild Oat Herbicide	**0.73 kg a.i./ha** (1.2 L/ha) **+ 0.70-0.85 kg a.i./ha** (3.5-4.2 L/ha)	broadleaf weeds controlled or suppressed by Estaprop XT Liquid Herbicide alone at the same rate + wild oats
Estaprop XT Liquid Herbicide + Everest Solupak 70 DF Herbicide + surfactant	**0.73 kg a.i./ha** (1.2 L/ha) **+ 0.014-0.028 kg a.i./ha** (21.5-43 g/ha) **+ 0.25% v/v**	broadleaf weeds controlled or suppressed by Estaprop XT Liquid Herbicide alone at the same rate + weeds controlled by Everest Solupak 70 DF Herbicide + surfactant at the same rate
Estaprop XT Liquid Herbicide + Horizon 240EC Herbicide Tank Mix (clodinafop-propargyl + Score Adjuvant)	**0.73 kg a.i./ha** (1.2 L/ha) **+ 0.055-0.070 kg a.i./ha** (0.23-0.29 L/ha) **+ 0.8 to 1.0% v/v**	broadleaf weeds controlled or suppressed by Estaprop XT Liquid Herbicide alone at the same rate + grass weeds controlled by Horizon 240EC Herbicide Tank Mix at the same rate
Estaprop XT Liquid Herbicide + Puma^{120} Super	**0.73 kg a.i./ha** (1.2 L/ha) **+ 0.046-0.092 kg a.i./ha** (0.38-0.77 L/ha)	broadleaf weeds controlled or suppressed by Estaprop XT Liquid Herbicide alone at the same rate + grass weeds controlled by Puma^{120} Super at the same rate
Estaprop XT Liquid Herbicide + Vanquish	**2.6-5.2 kg a.i./ha** (4.2-8.4 L/ha) **+ 2.25-4.5 kg a.i./ha** (4.7-9.4 L/ha)	aspen, alder, cherry, balsam, poplar, basswood, birch, elm, bur oak, spruce, pine, fir, tamarack, and white cedar

The submitted efficacy data support the weed control claims summarized in Table 5.1.4 for Optica Trio applied in tank mix with Horizon 240EC Herbicide Tank Mix or Everest Solupak 70 DF.

Table 5.1.4 Weed Control and Suppression Claims for Optica Trio

Herbicide	Rate	Weeds Controlled	Weeds Suppressed
Optica Trio + Horizon 240EC Herbicide Tank Mix + Score Adjuvant)	**900 or 1500 g a.i./ha** (1.5 or 2.5 L/ha) + **56 g a.i./ha** (230 mL/ha) + 0.8% v/v	weeds controlled by Optica Trio alone at the same rate + wild oats, green foxtail (wild millet) and yellow foxtail	weeds suppressed by Optica Trio alone at the same rate
Optica Trio + Everest Solupak 70 DF	**900 or 1500 g a.i./ha** (1.5 or 2.5 L/ha) + **30 g a.i./ha** (43 g/ha)	weeds controlled by Optica Trio alone at the same rate + wild oats and green foxtail (wild millet)	weeds suppressed by Optica Trio alone at the same rate
	900 or 1500 g a.i./ha (1.5 or 2.5 L/ha) + **15 g a.i./ha** (21.5 g/ha)	weeds controlled by Optica Trio alone at the same rate + green foxtail only (wild millet)	weeds suppressed by Optica Trio alone at the same rate

5.1.5 Water Volume

Estaprop XT Liquid Herbicide

Applications were made using water carrier volumes of 50-110 L/ha. It is acceptable to recommend a spray volume for ground application ranging between 50-200 L/ha since the currently registered dichlorprop + 2,4-D end-use products have recommended spray volumes ranging between 50-200 L/ha. For aerial application, the data provided supports the minimum water volume of 30 L/ha, as the performance of the new isomer dichlorprop-P was similar to that of the racemic mixture dichlorprop at 50 L/ha. This spray volume is considered acceptable for simulating an aerial application treatment in a ground application trial.

Optica Trio

Treatments were applied using water carrier volumes of 93.5 - 250 L/ha. It is acceptable to recommend a spray volume ranging between 50 - 200 L/ha since currently registered dichlorprop + 2,4-D end-use products have recommended spray volumes ranging between 50 - 200 L/ha.

Supported Water Volumes

The data support a minimum water volume of 50 L/ha for application by ground of Optica Trio.

5.2 Phytotoxicity to Host Plants

Estaprop XT Liquid Herbicide

Data from 23 replicated field trials (barley in 11 trials, spring wheat in 9 trials, and durum wheat in 5 trials) conducted at multiple locations over a 2-year period in Alberta, Saskatchewan, and Manitoba, were submitted in support of the host crop tolerance claims. Some trials included multiple crops. Application rates ranged from the 1X to 1.4X rate.

Crop injury percent was visually assessed up to three times during the growing season. Crop yield, expressed as a percentage of an untreated weedy check or a grass-free check, was reported in each trial.

Optica Trio

Data from 92 replicated field trials (spring wheat in 36 trials, durum wheat in 11 trials, winter wheat in 15 trials, spring barley in 18 trials and oats in 15 trials) conducted at multiple locations over a 2-year period in Alberta, Saskatchewan, Manitoba, Ontario, Québec and Prince Edward Island, were submitted in support of the host crop tolerance claims. Optica Trio was applied at rates ranging from 900 g a.i./ha to 3000 g a.i./ha in the field trials designed to assess crop safety at the proposed and potential overlap rates. Some trials included multiple crops.

Crop injury percent was visually assessed up to four times during the growing season. Crop yield, expressed as a percentage of the untreated weedy check, was reported in 79 trials.

5.2.1 Acceptable Claims for Host Plants

The tolerance of barley, spring wheat and durum wheat was acceptable following a post-emergence application of Estaprop XT Liquid Herbicide and was comparable to that of Estaprop Liquid Herbicide, when applied alone or in a tank-mix.

No data were provided in support of winter wheat. However, it can be extrapolated that crop tolerance would also be acceptable for this crop. Therefore, the use patterns as presented on the label are supported.

Optica Trio applied alone did not result in significant crop injury or a reduction in yield to wheat (spring, durum and winter), barley and oats. Optica Trio applied in tank mix with Everest Solupak 70 DF or Horizon 240EC Herbicide Tank Mix did not result in significant crop injury or a reduction in yield to spring wheat. The use patterns as presented on the label are supported.

5.3 Impact on Succeeding Crops

Given that Estaprop XT Liquid Herbicide and Estaprop Liquid Herbicide have been shown to be agronomically equivalent, and that Estaprop Liquid Herbicide does not have any recropping restrictions, it is not expected that Estaprop XT Liquid Herbicide would result in crop injury or a reduction in yield to rotational crops seeded the year after an application of Estaprop XT Liquid Herbicide, therefore no rotational cropping restrictions on the label are required.

A scientific rationale was provided to address the impact of Optica Trio on succeeding crops. The impact of MCPA and mecoprop-P on succeeding crops has already been well established. It is not expected that dichlorprop-P would result in crop injury or a reduction in yield to rotational crops seeded the year after an application of Optica Trio based on the facts that the half-life of dichlorprop-P averaged less than four days and that the currently registered dichlorprop + 2,4-D end-use products have no recropping restrictions. Therefore, it is supported that no rotational cropping restrictions are required on the label.

5.4 Sustainability

5.4.1 Survey of Alternatives

There are many Group 2, 4, 5, 6, and 7 herbicides that control broadleaf weeds in cereals and several herbicides are registered for brush control.

5.4.2 Compatibility with Current Management Practices Including Integrated Pest Management

Estaprop XT Liquid Herbicide offers broad-spectrum weed control when used as a post-emergence herbicide in wheat (spring, durum and winter), barley, non-crop areas and for brush control. It is compatible with integrated weed management practices because it controls a range of broadleaf weeds with a single application and because its post-emergence application timing permits an assessment of whether this herbicide is suitable for the particular weed species present in the field. It is compatible with both conservation tillage and conventional production systems.

Optica Trio offers broad-spectrum weed control when used as a post-emergence herbicide in wheat (spring, durum and winter), barley and oats. It is compatible with integrated weed management practices because it controls a range of broadleaf weeds with a single application and because its post-emergence application timing permits an assessment of whether this herbicide is suitable for the particular weed species present in the field. It is compatible with both conservation tillage and conventional production systems.

5.4.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Repeated use of herbicides having the same mode of action in a weed control program increases the probability of selecting naturally resistant biotypes. Estaprop XT Liquid Herbicide will provide an alternative for growers to Group 2 chemistries. Optica Trio will provide an alternative for growers to Group 2, 5, 6, and 7 chemistries.

The Estaprop XT Liquid Herbicide label and the Optica Trio label include the resistance management statements, as per Regulatory Directive DIR99-06, *Voluntary Pesticide Resistance-Management Labelling Based on Target Site/Mode of Action*.

5.4.4 Contribution to Risk Reduction and Sustainability

The use of the optically pure form of 2,4-DP-p could potentially result in reduced environmental loading relative to the current use of the racemic form of dichlorprop.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e. persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, dichlorprop-P and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[3] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

Dichlorprop-P does not meet all Track 1 criteria, and is not considered a Track 1 substance. See Table 6 Appendix I for comparison with Track 1 criteria. Dichlorprop-P will not form any transformation products which meet the Track 1 criteria.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.[4] The list is used as described in the PMRA Notice of Intent NOI2005-01[5] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02,[6] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act*

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[3] DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

[4] *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

[5] NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.*

[6] DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

(substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

Technical grade dichlorprop-P and the end-use product Optica Trio do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.

The end-use product Estaprop XT Liquid Herbicide does not contain any formulants of health or environmental concern identified in the *Canada Gazette*. However, the end-use product does contain aromatic petroleum distillates. Therefore, the label for Estaprop XT Liquid Herbicide will include the statement: "This product contains aromatic petroleum distillates that are toxic to aquatic organisms."

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for 2,4-DP-P and 2,4-DP-P EHE, in conjunction with data on the racemic form of 2,4-DP, is adequate to define the majority of toxic effects that may result from exposure to these compounds. In short- and long-term studies on laboratory animals, the primary targets were the liver and kidneys with mild anaemia seen in some species. There was no evidence of carcinogenicity in rats or mice after longer-term dosing. There was no evidence of developmental toxicity, although reproductive and offspring toxicity was observed at test doses that also induced maternal toxicity. 2,4-DP-P is not considered to be a neurotoxicant.

The nature of the residue in wheat plants and animals is adequately understood. The residue definition is dichlorprop. The use of dichlorprop-P on wheat, barley and oats does not constitute an unacceptable chronic or acute dietary risk (food and drinking water) to any segment of the population, including infants, children, adults and seniors. Sufficient crop residue data have been reviewed to recommend maximum residue limits to protect human health. The PMRA recommends that the following maximum residue limits be specified for:

Commodity	Recommended MRL
Crop group 15 (Cereal grain)	0.02 ppm
Milk	0.01 ppm
Eggs; Fat and Meat of cattle, goats, hogs, horses, poultry and sheep	0.02 ppm
Meat by-products of cattle, goats, hogs, horses, poultry and sheep	0.05 ppm

When 2,4-DP-P end-use products are used according to label directions, mixers, loaders and applicators and workers re-entering treated areas are not expected to be exposed to levels of 2,4-DP-P that will result in an unacceptable risk. The personal protective equipment on the product label is adequate to protect workers.

7.2 Environmental Risk

Although dichlorprop-P does not pose any unacceptable environmental risks except for non-target terrestrial plants and on-field beneficial arthropods, the use of Estaprop XT Liquid Herbicide and Optica Trio may pose a risk to terrestrial and aquatic plants due to the presence of other active ingredients present in the these products. End-use products that are comprised of more than one active ingredient can exhibit different toxicity profiles than end-use products formulated with a single active ingredient. Terrestrial and aquatic buffer zones were calculated with consideration of the actives used as co-formulants in the various end-use products and based upon the maximum seasonal application rates for each product.

Precautionary statements appear on the product labels to identify and mitigate the risk from spray drift to terrestrial and aquatic plants. For Estaprop XT Liquid Herbicide, terrestrial buffer zones of 2 – 350 metres and aquatic buffer zones of 1-200 metres are required to protect sensitive non-target plant species from spray drift. For Optica Trio (co-formulated with mecoprop-P and MCPA), terrestrial buffer zones of two metres and aquatic buffer zones of one metre appear on the label.

All product labels contain and advisory statement to reduce the potential risk from runoff.

7.3 Value

The data submitted to register Estaprop XT Liquid Herbicide are adequate to describe its efficacy for use in wheat (spring, durum and winter), barley, non-crop areas, and for brush control. Estaprop XT Liquid Herbicide provides control of 59 herbaceous broadleaf weed species (including annuals and perennials) and 35 woody species (including coniferous and deciduous species). Host tolerance and yield response to the application of Estaprop XT Liquid Herbicide to cereal crops is also acceptable. The use of the isomer dichlorprop-P 2-ethylhexyl ester rather than the racemic dichlorprop 2-ethylhexyl ester facilitates a higher active ingredient loading in the formulation. This allows a reduction in rate of product applied per hectare.

The data submitted to register Optica Trio are adequate to describe its efficacy for use in wheat (spring, durum and winter), barley and oats. Optica Trio provides control of stinkweed, wild mustard, lamb's-quarters, volunteer canola, common chickweed, wild buckwheat, redroot pigweed, kochia, common ragweed, cleavers, and suppression of lady's thumb and Canada thistle (top growth suppression), with a single application to wheat (spring, durum, winter), barley and oats. Host tolerance and yield response to the application of Optica Trio is also acceptable.

8.0 Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of A H Marks 2,4-DP-P 2EH Ester (Technical) and A H Marks 2,4-DP-P Technical Acid and Optica Trio containing the technical grade active ingredients MCPA, dichlorprop-P and mecoprop-P, to control broadleaf weeds in wheat (spring, durum and winter), barley and oats and Estaprop XT Liquid Herbicide containing the technical grade active ingredients dichlorprop-P and 2,4-D (both present as 2-ethylhexyl ester) to control broadleaf weeds and brush in wheat, industrial and non-crop land.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

2, 4-D	2, 4-dichlorophenoxy acetic acid
2,4-DP	2,4-dichlorprop
2, 4-DP-P	2, 4-Dichlorprop-P
2,4-DP-P EHE	2,4-dichlorprop-P 2-ethylhexyl ester
µg	micrograms
a.i.	active ingredient
a.e.	acid equivalent
abs	absolute
AD	administrated dose
ADI	acceptable daily intake
ARfD	acute reference dose
BAF	bioaccumulation factor
BBCH	growth development stages for cereals
BCF	Bioconcentration Factor
bw	body weight
bwg	body weight gain
CAS	Chemical Abstracts Service
CAF	composite assessment factor
CEPA	Canadian Environmental Protection Act
cm	centimetres
CR	chemical resistant
DF	dry flowable
DFR	dislodgeable entry interval
DMA	dimethyl-amine salt
DNA	deoxyribonucleic acid
EC_{25}	effective concentration on 25% of the population
EC_{50}	effective concentration on 50% of the population
EDE	estimated daily exposure
EEC	estimated environmental exposure concentration
EP	end-use product
FDA	Food and Drugs Act
FIR	food ingestion rate
FOB	functional observation battery
g	gram
GAP	Good Agricultural Practices
GC-MSD	gas chromatography methods with mass spectrometric detection
GIT	gastro-intestinal tract
h/hr	hour
ha	hectare(s)
HAFT	highest average field trial residue level
HDT	highest dose tested
HPLC	high performance liquid chromatography
IUPAC	International Union of Pure and Applied Chemistry
K	Henry's Law Constant

kg	kilogram
K_d	soil-water partition coefficient
K_{oc}	organic-carbon partition coefficient
K_{ow}	*n*–octanol-water partition coefficient
L	litre
Lb	pound
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOAEL	lowest observed adverse effect level
LOC	level of concern
LOD	level of death
LOQ	limit of quantitation
LR_{50}	lethal rate 50%
m	metre
mg	milligram
mL	millilitre
M/L/A	mixer/loader/applicator
MAS	maximum average score
MCPA	4-chloro-2-methylphenoxy)acetic acid
MIS	maximum irritation score
MOE	margin of exposure
MRL	maximum residue limit
MS	mass spectrometry
N/A	not applicable
nm	nano metre
NAFTA	North American Free Trade Agreement
NOAEL	no observed adverse effect level
NOAEC	no observed adverse effect concentration
NOEC	no observed effect concentration
NZW	New Zealand white
OCDD	octa-chlorinated dibenzo-P-dioxin
OCDF	octa-chlorinated dibenzofuran
Pa	Pascal
pKa	dissociation constant
PACR	proposed acceptability for continuing registration
PCDD	polychlorinated dibenzodioxin
PCDF	furan
PHED	pesticide handler exposure database
PHI	preharvest interval
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppb	parts per billion
ppm	parts per million
PRVD	proposed re-evaluation decision
RBC	red blood cell count
RED	re-evaluation
rel	relative

REI	restricted entry interval
RQ	risk quotient
RRD	re-evaluation decision document
RVD	re-evaluation decision
STMdR	supervised trial median residue
STMR	supervised trial mean residue
$t_{1/2}$	half-life
TC	transfer coefficient
TGAI	technical grade active ingredient
TRR	total radioactive residue
TSMP	Toxic Substances Management Policy
UF	uncertainty factor
US	United States
USEPA	United States Environmental Protection Agency
UV	ultraviolet
v/v	volume per volume dilution
wt	weight

Appendix I Tables and Figures

Table 1 Acute Toxicity of 2,4-dichlorprop-P and Its Associated End-use Products (Optia Trio, Estaprop XT Liquid Herbicide)

ACUTE STUDIES - TECHNICAL (2,4-dichlorprop-P)				
Study type	Species, strain	Results	Comments	PMRA #
Oral	rat, Sprague Dawley CD	LD_{50} ♂ = 567 (354-779) ♀ = 567 (354-779) ♂♀ = 567 (391-743) mg/kg bw	Moderate toxicity **WARNING - POISON**	1097063
Dermal	rat, Wistar	LD_{50} >4000 mg/kg bw	Low toxicity	1190440
	rat, Sprague Dawley CD	LD_{50} >2000 mg/kg bw	Low toxicity	1097065
Inhalation (head/nose)	rat, Wistar	LC_{50} >7.4 mg/L	Low toxicity	1097066
	rat, Sprague Dawley CD	LC_{50} >2.7 mg/L	Low toxicity	1097067
Eye irritation	rabbit, New Zealand white (NZW)	MIS[a] at 72 h = 95/110 MAS[b] = 80.3/110	mildly irritating **DANGER - CORROSIVE TO EYE**	1097068
Skin irritation	rabbit, NZW	MAS = 0.1/8	Slightly irritating	1097050
Skin sensitization (maximization)	guinea pig, Dunkin Hartley	negative	Not a skin sensitizer	1097051
ACUTE STUDIES - TECHNICAL (2,4-dichlorprop-P 2 ethylhexyl ester)				
Oral	rat, Sprague Dawley CD	LD_{50} ♂ = 776 (634-949) ♀ = 876 (716-1080) ♂♀ = 824 (715-951) mg/kg bw	Moderate toxicity **WARNING - POISON**	1094282
Dermal	rabbit, NZW	LD_{50} >2000 mg/kg bw	Low toxicity	1094283
Inhalation (whole-body)	rat, Sprague Dawley CD	LC_{50} = 4.1mg/L	Low toxicity	1094284
Eye irritation	rabbit, NZW	MIS at 1 h = 9.7/110 MAS = 2.6/110	minimally irritating	1094285
Skin irritation	rabbit, NZW	MIS at 48 h = 1.5/8 MAS = 1.2/8	Slightly irritating	1094286
Skin sensitization (maximization)	guinea pig, Dunkin Hartley Pirbright white		Potential skin sensitizer	1094287

ACUTE STUDIES - FORMULATION (Optia Trio)				
Oral	rat, Sprague Dawley	LD_{50}: ♂ = 1106 (828-1477) ♀ = 1059 (797-1405) ♂♀ = 1083 (823-1424) mg/kg bw	Low toxicity	1094798
Dermal	rat, Sprague Dawley	LD_{50} >4000 mg/kg bw	Low toxicity	1094799
Inhalation	waiver request	Expected to be LC_{50} >2 mg/L	Expected to be of low toxicity	1094800
Eye irritation	rabbit, NZW	MIS at 24h = 52/110 MAS = 37/110	Extremely irritating DANGER - EYE IRRITANT	1094801
Skin irritation	rabbit, NZW	MIS at 72 h = 1.3/8 MAS = 0/8	Slightly irritating	1094802
Skin sensitization (maximization)	guinea pig, Dunkin Hartley	negative	Not a dermal sensitizer	1094803
ACUTE STUDIES - FORMULATION (Estaprop XT Liquid Herbicide, Sub No 2005-3580)				
Oral	rat, Sprague Dawley	LD_{50}: ♂ = 943 (904-982); ♀ = 747 (465-1076); ♂♀ = 926 (897-955) mg/kg bw	Moderate toxicity **WARNING POISON**	793054
Dermal	rat, Sprague Dawley	LD_{50} >2000 mg/kg bw	Low toxicity	793055
Inhalation	rat, Sprague Dawley	LC_{50} >2.6 mgL	Low toxicity	793056
Eye irritation	rabbit, NZW	MIS at 24h = 11.3/110 MAS = 5.9/110	Minimally irritating	793057
Skin irritation	rabbit, NZW	MIS at 1 h = 3/8 MAS = 0.6/8	Mildly irritating **CAUTION – SKIN IRRITANT**	793061
Skin sensitization (Buehler)	guinea pig, Hartley albino	negative	Not a dermal sensitizer	793065
[a] MIS = maximum irritation score; [b] MAS = maximum average score for 24, 48 and 72 hours				

Table 2 Toxicity Profile of Technical 2,4-DP-P, 2,4-DP racemate, and 2,4-DP-P EHE

SHORT-TERM TOXICITY (2,4-DP-P, 2,4-DP racemate, 2,4-DP-P EHE)			
Study type	**Species, strain / Test compound / dose levels**	**Results and comments**	**PMRA#**
28-day dietary	Rat, Wistar, Chbb = THOM (SPF) 0, 100 (2,4-DP), 100 (2,4-DP D-form), 500 (2,4-DP), 500 (2,4-DP D-form) (Note: 2,4-DP D-form = 2,4-DP-P) ♂ = 0, 10.6, 10.8, 52.6, 52.0; ♀ = 0, 10.8, 10.7, 53.6, 52.8 mg/kg bw/d	NOAEL = 500 ppm (♂♀ = 53 mg/kg bw/d), HDT (♂ - ↑ kidney wt in 2,4-DP at 100 and 500 ppm; not considered adverse because no gross or histopathological alterations)	1651613
90-day dietary	mouse; B6C3F1 2,4-DP-P 0, 100, 1000, 2500 ppm ♂ = 0, 20, 224, 683; ♀ = 0, 33, 380, 1043 mg/kg bw/d	NOAEL = 1000 ppm; ♂ = 224, ♀ = 380 mg/kg bw/d, HDT LOAEL = 2500 ppm (♂♀ - ↑ AP, cyanide-insensitive palmitoyl-CoA-oxidatiion; pathology of liver (↑ liver wt, abs & rel, dark-brown discoloration, eosinophilic hepatocyte) and kidneys (cytoplasmic eosinophilia in renal tubule cells) ♂ - ↓ bw, bwg, food intake ♀ - ↑ cholesterol	1097053
90-day dietary / neurotoxicity	rat, Wistar 2,4-DP-P 0, 100, 500, 2000 (♂), 3000 (♀) ppm ♂= 0, 7, 35, 144; ♀ = 0, 8, 42, 245 mg/kg bw/d	NOAEL = 500 ppm; ♂ = 35, ♀ = 42 mg/kg bw/d LOAEL : ♂ = 2000 ppm (144 mg/kg bw/d), ♀ = 3000 ppm (245 mg/kg bw/d) (↓ bw, bwg, food intake; ↑ water intake; hematology and clinical chemistry alterations; pathology of liver and kidneys)	1107538
90-day dietary	dog, beagle 2,4-DP-P 0, 25, 175, 525 ppm; ♂ = 0, 0.7, 5.1, 15.7 ♀ = 0, 0.8, 5.8, 18.1 mg/kg bw/d	NOAEL = 175 ppm; ♂ = 5.1, ♀ = 5.8 mg/kg bw/d LOAEL = 525 ppm; ♂ = 15.7, ♀ = 18.1 mg/kg bw/d (diarrhea, ↓ RBC)	1097055
1-year dietary	dog, beagle 2,4-DP-P 0, 120, 240, 720 ppm ♂ = 0, 3.5, 7.0, 22.2 ♀ = 0, 3.9, 7.7, 26.0 mg/kg bw/d	NOAEL: 240 ppm; ♂ = 7.0 , ♀ = 7.7 mg/kg bw/d LOAEL: 720 ppm; ♂ = 22; ♀ = 26.0 mg/kg bw/d (diarrhea; ↓ bwg; hematology and clinical chemistry alteration; GIT ulceration)	1097056
21-day dermal	rabbit, NZW 2,4-DP-P 0. 10, 100, 1000 mg/kg bw	NOAEL: localized toxicity - not established systemic toxicity = 1000 mg/kg bw/d LOAEL: localized systemic toxicity = 10 mg/kg bw/d (erythema, diffuse acanthosis, diffuse inflammatory cells in superficial dermis)	1097057
4-week dermal	rat, Wistar 2,4-DP-P EHE 0, 15, 150, 1000 mg/kg bw/d	NOAEL: localized toxicity = 150 mg/kg bw/d systemic toxicity: 1000 mg/kg bw/d LOAEL: localized toxicity = 1000 mg/kg bw/d (erythema with or without scaling)	1094288

CHRONIC TOXICITY AND ONCOGENICITY			
18-month dietary oncogenicity	Mouse 2,4-DP-P 0, 40, 400, 800 (♀), 2000 (♂), 3500 (♀) ppm ♂ = 0, 6.8, 64.5, 384.7 ♀ = 0, 8.7, 88.3, 1488 mg/kg bw/d	NOAEL = 40 ppm; ♂ = 6.8, ♀ = 8.7 mg/kg bw/d LOAEL = 400 ppm; ♂ = 64.5, ♀ = 88.3 mg/kg bw/d (↓ bw, bwg, food intake; kidney pathology) no evidence of oncogenicity	1097058 1097059
2-year dietary/ oncogenicity	rat, Fischer 344 2,4-DP 0, 100, 300, 1000, 3000 ppm ♂ = 0, 3.6, 11.0, 36.5, 116.1 ♀ = 0, 4.4, 13.1, 45.7, 147.0 mg/kg bw/d	NOAEL = 300 ppm; ♂ = 11.0, ♀ = 13.1 mg/kg bw/d LOAEL = 1000 ppm; ♂ = 36.5, ♀ = 45.7 mg/kg bw/d (↓ bw, bwg, food intake; hematology and clinical chemistry alterations; liver and kidney pathology) no evidence of oncogenicity	1097060 1288187 1288189
REPRODUCTION AND DEVELOPMENTAL TOXICITY			
reproductive toxicity – preliminary	rat, Wistar 2,4-DP-P 0, 1200, 1500, 1800 ppm ♀ = 0, 101, 128, 152 mg/kg bw/d	no NOAEL was set because this was a preliminary range-finding study maternal toxicity: ≥1200 ppm - ♂ ↓ food intake; ♀ ↓ bw, bwg (gestation) offspring toxicity: 1800 ppm - ↓ pup/litter wt	1097039
2-generation reproductive toxicity	rat, Wistar 2,4-DP 0, 80, 400, 2000 ppm ♂, F_0 = 0, 8.2, 40.9, 206.5 F_1 = 0, 7.8, 39.2, 232.7 ♀ F_0 = 0, 8.9, 44.3, 218.1 F_1 = 0, 8.4, 41.7, 247.8 mg/kg bw/d	NOAEL: parental systemic, offspring, & reproductive toxicity = 400 ppm; ♂ = 40, ♀ = 42 mg/kg bw/d LOAELs: parental systemic, offspring, & reproductive toxicity = 2000 ppm; ♂ = 207, ♀ = 218 mg/kg bw/d (maternal toxicity: ↓ bw, food intake, hematology and clinical chemistry alteration; offspring toxicity: stillborns, death, dilated renal pelvis; ↓ bw, bwg; delayed maturation reproductive toxicity: ↑ gestation, stillbirths, total litter loss; ↓ litter size, maternal pup care)	1097038 1097076
Developmental toxicity	rat, Wistar 2,4-DP-P 0, 20, 80, 160 mg/kg bw/d	NOAELs: maternal toxicity = 20 mg/kg bw/d developmental toxicity = 80 mg/kg bw/d LOAELs: maternal toxicity = 80 mg/kg bw/d (↓ bw, bwg, food intake) developmental toxicity = 160 mg/kg bw/d (↓ fetal wt; ↑ skeletal variation/retardation)	1097040
Developmental toxicity	rabbit, NZW 2,4-DP-P 0, 20, 50, 100 mg/kg bw/d	NOAELs: maternal & developmental toxicity = 50 mg/kg bw/d LOAELs: maternal & developmental toxicity = 100 mg/kg bw/d (maternal toxicity - ↓ bw, food intake; stomach ulceration developmental toxicity - ↑ skeletal variation; ↓ male fetuses)	1097041

GENOTOXICITY			
Study	**Species and strain or cell type / Test compound / Concentrations or doses**	**Results**	**PMRA#**
Gene mutations in bacteria	*Salmonella* Typhimurium strains TA 98, TA 100, TA 1535 and TA 1537 2,4-DP-P	negative	1097042
	Salmonella Typhimurium strains TA 98, TA 100, TA 1535 and TA 1537 2,4-DP-P 2-EHE	negative	1094277
Gene mutations in mammalian cells in vitro	Chinese hamster ovary cells (HGPRT locus) 2,4-DP-P	negative	1097035
	Chinese hamster ovary cells (HGPRT locus) 2,4-DP-P EHE	negative	1094279
Chromosome aberrations in vitro	human blood lymphocytes 2,4-DP-P	+S9: negative -S9: divergent results at cytotoxic and non-cytotoxic concentrations; inconsistent finding; lack of clear evidence of genotoxicity	1097036
	human blood lymphocytes 2,4-DP-P	negative	1097037
	human blood lymphocytes 2,4-DP-P 2-EHE	negative	1094280
in vitro/in vivo unscheduled DNA synthesis	rat, Wistar; bone marrow cells 2,4-DP-P	negative	1097045
Micronucleus assay (in vivo)	mouse, CD-1, ♂♀ 24 h: 0, 4, 20,100 48 & 72 h: 0, 100 mg/kg bw 2,4-DP-P	negative	1097044
	mouse, CD-1, ♂♀ 24, 48, 72 h: 0, 250, 500, 1000 mg/kg bw 2,4-DP-P 2-EHE	negative	1094278

SPECIAL STUDIES			
Study type	**Species/strain/ test compound/dose levels**	**Results and comments**	**PMRA#**
acute neurotoxicity	rat, Wistar 2,4-DP-P 0, 0, 125, 250, 400 (♂), 500 mg/kg bw	NOAELs: acute neurotoxicity = 500 mg/kg bw, HDT systemic toxicity = 125 mg/kg bw LOAELs: systemic toxicity = 250 mg/kg bw (FOB & motor activity effects)	1190047
Metabolism	Rat, Wistar 2,4-DP-P 2,4-DP-P EHE	Absorption: rapid and extensive; plasma peak concentrations seen ~2 h post-dosing; a secondary peak at ~6 h indicates a possible entero-hepatic recirculation. Distribution: only a small fraction remains in tissues, but no evidence of bioaccumulation. Excretion: rapid; mainly in the urine within 24 h; 4-12% administered dose eliminated in feces; not eliminated in expired air. Metabolism: minimal; unchanged parent compound the main compound excreted; other metabolites made up <3%.	1097046

Table 3 Toxicology Endpoints for Use in Health Risk Assessment for 2,4-DP-P and 2,4-dichlorprop-P 2 ethylhexyl ester

Exposure scenario	Dose (mg/kg bw/d)	Study	Endpoint	UF/SF[1] pr Target MOE[2]
Acute dietary, all population	NOAEL = 7.0	1-year dog	Irritation of mucous membranes	100X
	ARfD = 0.07 mg/kg bw			
Chronic dietary	NOAEL = 6.8	18-month mouse oncogenicity	Chronic nephropathy	100X
	ADI = 0.07 mg/kg bw/d			
Short-term dermal	NOAEL = 1000	21-day rabbit or 4-week rat dermal	No systemic effects	100X
Short- and intermediate-term inhalation	NOAEL = 7	1-year dog	Irritation of mucous membranes	100X

[1] Dietary scenerios

[2] Exposure scenerios

Table 4 Residue Analysis

Matrix	Method ID	Analyte	Method Type	LOQ		Reference
Plant Matrices						
Grass and Cereals	Method 591	2,4-DB 2,4-D 2,4-DCP 2,4-DP-p (dichlorprop-P)	GC-MSD	0.05 ppm per analyte	Grass Wheat whole plant Barley whole plant Wheat grain Barley grain Wheat straw Barley straw	PMRA# 1329391 PMRA# 1329394
	ILV of Method 591					PMRA# 1329392
Note: Due to low recoveries, Method 591 is **not acceptable** for the determination of residues of 2,4-DCP in grass and cereals.						
Cereals	Method AR 258-00	MCPP-p (mecoprop-P) 2,4-DP-p (dichlorprop-P)	GC-MSD	0.02 ppm per analyte	Wheat grain	PMRA# 1284387
	ILV of Method AR 258-00			0.05 ppm per analyte	Wheat green plant Wheat straw	PMRA# 1284390
Animal Matrices						
Bovine matrices: whole milk, meat, fat, liver and kidney **Poultry matrices:** whole egg and chicken meat	Method AR 125-96	MCPP-p (mecoprop-P) 2,4-DP-p (dichlorprop-P)	HPLC-UV LC-MS/MS (confirmatory)	0.01 ppm 0.02 ppm 0.05 ppm (per analyte)	Milk Meat, fat and egg Liver and kidney	PMRA# 1284390
	ILV of Method AR 125-96					PMRA# 1284392

Matrix	Method ID	Analyte	Method Type	LOQ	Reference
NATURE OF THE RESIDUE IN SPRING WHEAT					**PMRA # 1098608 and 1098609**

Radiolabel Position	[Phenyl-U-^{14}C]Dichlorprop-P
Test Site	Outdoor plots
Treatment	A single foliar spray application at the BBCH 31 growth stage
Rate	750 g a.e./ha
End-use product	Dichlorprop-P formulated as the potassium salt
Preharvest interval	0, 28 and 89 days

Matrix		**PHI (days)**	[Phenyl-U-^{14}C]
			TRRs (ppm)
Immature plants (foliage)	Surface wash	0	18.270
	Washed tissue		5.343
	Total		**26.613**
Immature foliage	Surface wash	28	0.055
	Washed tissue		2.254
	Total		**2.310**
Immature ears			**0.109**
Mature straw	Surface wash	89	0.036
	Washed tissue		1.336
	Total		**1.372**
Mature grain			**0.021**

Metabolites Identified	**Major Metabolites (> 10% of the TRRs)**	**Minor Metabolites (< 10% of the TRRs)**
Radiolabel Position	[Phenyl-U-^{14}C]	[Phenyl-U-^{14}C]
Immature plant	Dichlorprop-P	None
Immature foliage	Metabolite 5 (dichlorprop-OH) Metabolite 8 (glucoside conjugate)	Dichlorprop-P 2,4-dichlorophenol Metabolite 1 Metabolite 2 Metabolite 3 Metabolite 4 Metabolite 6 Metabolite 7 Metabolite 9 Metabolite 11
Immature ears	Dichlorprop-P Metabolite 4 (unknown)	Metabolite 1 Metabolite 5 (dichlorprop-OH) Metabolite 6 Metabolite 7 Metabolite 9 Metabolite 12
Mature straw	Dichlorprop-P Metabolite 8 (glucoside conjugate) Metabolite 11 (methyl ester of dichlorprop)	2,4-dichlorophenol Metabolite 1 Metabolite 2 Metabolite 4 Metabolite 5 (dichlorprop-OH) Metabolite 7

Matrix	Method ID	Analyte	Method Type	LOQ	Reference
				Metabolite 9 Metabolite 10 Metabolite 12	
Mature grain	38.9% of the TRRs (0.008 ppm) were extractable. Residues too low and were not further analyzed.				

Metabolism within the wheat plant was extensive producing a wide range of metabolites. In addition to dichlorprop-P and 2,4-dichlorophenol, 13 different radioactive components were found in wheat samples. The major metabolite found, Metabolite 8, was demonstrated to be a sugar conjugate where the conjugating moiety involved was not glucose but probably higher glycosides. Metabolite 5 was demonstrated to be a hydroxylated derivative of dichlorprop and Metabolite 11, the methyl ester of dichlorprop. A number of other metabolites were characterized including two glucose conjugates (Metabolites 2 and 3), a highly-polar acid-labile component which was probably a conjugate (Metabolite 1) and up to five unidentified components present at low levels.

CONFINED ACCUMULATION IN ROTATIONAL CROPS	PMRA # 1295906

The registrant submitted a rationale to waive the requirement of a confined crop rotational study.

Based on the facts that:

- Dichlorprop-P residues in soil are not expected above the LOQ of 0.01 ppm 30 days after application;
- Degradation products are not available for uptake from the soil by rotational crops;
- Metabolism in soil follows the same first steps as the wheat metabolism, it is likely that the metabolism in secondary crops would follow that same pathways as the primary crop wheat and the metabolism would be just more extensive thus no significant residues are expected in the edible portions of rotational crops at the plant-back interval of 30 days.

The requirement for a confined crop rotational study can be waived.
A plant-back interval of 30 days for all crops must be added to the end-use product labels.

NATURE OF THE RESIDUE IN LAYING HEN	PMRA # 1288193

The registrant submitted a rationale to waive the requirement of a poultry metabolism study.

Based on the facts that:

- Studies in Europe show that 2,4-DP-p is present in small grains (barley, oats, wheat) at concentrations close to or below the limit of determination.
- Results from Canadian trials confirm that residues are expected to be consistently below 0.01 ppm in grain.
- Metabolism experiments in rat and goat show that 2,4-DP-p is rapidly absorbed from the gastrointestinal tract and equally rapidly excreted, mostly in an unchanged form. The small extent of metabolism observed consists of the formation of conjugates, which further assist excretion.
- Given the very low anticipated intake and the lack of tissue accumulation in other species, it is not expected that significant information would be gained from a poultry metabolism study.

The requirement for a poultry metabolism study can be waived.

NATURE OF THE RESIDUE IN LACTATING GOAT	PMRA # 1098607

Two lactating goats were administered two daily oral doses of [phenyl-U-^{14}C]dichlorprop-P in gelatin capsules for 7 consecutive days at daily doses equivalent to dietary levels of 5 ppm or 50 ppm, respectively. The goats were sacrificed approximately 16 hours after the final dose.

The overall recovery of the total administered radioactivity was 104% for the low dose and 93% for the high dose. Urinary excretion was the major route of elimination and accounted for 87% and 75% of the administered dose (AD) for the 5 ppm and 50 ppm dose levels, respectively. Excretion in feces accounted for 13% and 12% of the

Matrix	Method ID	Analyte	Method Type	LOQ	Reference

AD for the low dose and the high dose levels, respectively. Cage wash accounted for 5% of the AD for the low dose and 6% of the AD for the high dose.

Dichlorprop-P was found to be well absorbed by ruminants and excreted predominantly in the urine, as the unchanged compound. There was no evidence of accumulation of radioactivity in milk and edible tissues. Subsequent extraction and analysis of excreta and tissues showed that dichlorprop-P was the major and only residue identified, thus indicating that dichlorprop-P was not extensively metabolized.

Matrices	**% of Administered Dose**			
	[Phenyl-U-^{14}C]Dichlorprop-P			
	Low Dose: 5 ppm in Diet		High Dose: 50 ppm in Diet	
	%AD	ppm	%AD	ppm
Urine	86.85	--	75.29	--
Feces	12.68	--	12.39	--
Cage wash	4.67	--	5.56	--
Muscle	--	0.000	--	0.008
Fat	--	0.001	--	0.011
Kidney	0.008	0.036	0.011	0.488
Liver	0.005	0.004	0.006	0.047
Milk	0.01	--	0.01	--
Total	**104.22**	--	**93.27**	--

Metabolites identified	**Major Metabolites (> 10% of the TRRs)**	**Minor Metabolites (< 10% of the TRRs)**
Radiolabel Position	[Phenyl-U-^{14}C]	[Phenyl-U-^{14}C]
Renal fat	None	None
Liver	Dichlorprop-P	None
Kidney	Dichlorprop-P	None

FREEZER STORAGE STABILITY	**PMRA # 1288229 and 1288231**

The freezer storage stability data indicated that residues of 2,4-DCP, 2,4-D, 2,4-DB and 2,4-DP-p were stable at ≤-18°C for 18 months in barley green plant, straw and grain.

The freezer storage stability data indicated that residues of 2,4-DP-p 2-EHE and 2,4-DP-p were stable under frozen conditions for 10 months (300 days) in grass.

CROP FIELD TRIALS AND RESIDUE DECLINE IN WHEAT	**PMRA # 1461226, 1554767, 1754005 and 1754008**

In support of the end-use product Estaprop XT Liquid Herbicide

Sixteen field trials, including two decline trials, were conducted in Canada in spring wheat during the 2005 and 2006 growing seasons in locations satisfying the PMRA registration requirements [2 trials in Zone 5, 5 trials in Zone 7, 1 trial in Zone 7A and 8 trials in Zone 14].

At each test location, a single post-emergence foliar application of a co-formulation containing 2,4-DP-p 2-ethylhexyl ester and 2,4-D 2-ethylhexyl ester was made to spring wheat at the combined maximum rate of approximately 732 g a.e./ha (252 g 2,4-DP-p a.e./ha and 480 g 2,4-D a.e./ha). The application was made using ground equipment.

Forage samples were collected at preharvest intervals (PHIs) of 5 to 19 days; hay samples were collected at PHIs of 32 to 61 days; and, straw and grain samples were collected at crop maturity (PHIs of 58 to 109 days). At the decline sites, forage samples were collected at PHIs of 0, 1, 3, 7, 14 and 28 days and hay samples were cut at PHIs of 1, 3, 7, 14 and 28 days and left to dry in the field before being collected. No 0-day samples were collected for hay. Straw and grain samples were collected at PHIs of 30 days and at normal crop maturity (PHIs of 68 and 70 days). The wheat trials were conducted according to the Canadian GAP.

Commodity	Total Applic. Rate (g a.e./ha)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Dichlorprop-P									
Wheat forage	~252	5-19	32	<LOQ	1.82	1.77	0.61	0.75	0.51
Wheat hay		32-61	32	<LOQ	0.30	<0.28	<LOQ	<LOQ	–
Wheat grain		58-109	32	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Wheat straw		58-109	32	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
2,4-D									
Wheat forage	~480	5-19	32	<LOQ	9.47	8.51	3.14	3.51	2.78
Wheat hay		32-61	32	<LOQ	3.64	3.48	<LOQ	<0.62	0.82
Wheat grain		58-109	32	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Wheat straw		58-109	32	<LOQ	0.95	<0.60	<LOQ	<LOQ	–

In support of the end-use product OPTICA TRIO

Sixteen field trials, including two decline trials, were conducted in Canada in spring wheat during the 2006 and 2007 growing seasons in locations satisfying the PMRA registration requirements [2 trials in Zone 5, 5 trials in Zone 7, 1 trial in Zone 7A and 8 trials in Zone 14].

At each test location, a single post-emergence foliar application of Optica Trio, a co-formulation containing DMA salts of 2,4-DP-p, MCPA and mecoprop-P, was made when spring wheat was in the 2 to 5 leaf stage at the combined maximum rate of approximately 1500 g a.e./ha (772 g 2,4-DP-p a.e./ha, 399 g MCPA a.e./ha and 329 g MCPP-p a.e./ha). The application was made using ground equipment.

Forage samples were collected at PHIs of 8 to 25 days; hay samples were collected at PHIs of 26 to 49 days; and, straw and grain samples were collected at crop maturity (PHIs of 60 to 109 days). At the decline sites, forage samples were collected at PHIs of 0, 1, 3, 7, 14 and 28 days and hay samples were cut at PHIs of 1, 3, 7, 14 and 28 days and left to dry in the field before being collected. No 0-day samples were collected for hay. Straw and grain samples were collected at PHIs of 35 days and at normal crop maturity (PHIs of 60 and 77 days). The wheat trials were conducted according to the Canadian GAP.

Commodity	Total Applic. Rate (g a.e../ha)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Dichlorprop-P									
Wheat forage	~772	8-25	32	<LOQ	1.54	1.54	<LOQ	0.45	0.40
Wheat hay		26-49	32	<LOQ	1.38	1.29	<LOQ	0.35	0.27
Wheat grain		60-109	32	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Wheat straw		60-109	32	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
MCPA									
Wheat forage	~399	8-25	32	<LOQ	0.40	0.40	<LOQ	0.27	0.05
Wheat hay		26-49	32	<LOQ	0.47	0.43	<LOQ	0.26	0.05
Wheat grain		60-109	32	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Wheat straw		60-109	32	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
2-HMCPA									
Wheat forage	(~399 for MCPA)	8-25	32	<LOQ	0.29	0.29	<LOQ	0.25	0.01
Wheat hay		26-49	32	<LOQ	0.47	0.43	<LOQ	0.27	0.06
Wheat grain		60-109	32	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Wheat straw		60-109	32	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Mecoprop-P									
Wheat forage	~329	8-25	32	<LOQ	0.50	0.50	<LOQ	0.28	0.07
Wheat hay		26-49	32	<LOQ	0.54	0.53	<LOQ	0.27	0.07
Wheat grain		60-109	32	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Wheat straw		60-109	32	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0

CROP FIELD TRIALS AND RESIDUE DECLINE IN BARLEY	PMRA # 1461224, 1554768, 1753998 and 1754001

In support of the end-use product Estaprop XT Liquid Herbicide

Twelve field trials, including two decline trials, were conducted in Canada in barley during the 2005 and 2006 growing seasons in locations satisfying the PMRA registration requirements [1 trial in Zone 5, 1 trial in Zone 5B, 1 trial in Zone 7 and 9 trials in Zone 14].

At each test location, a single post-emergence foliar application of a co-formulation containing 2,4-DP-p 2-ethylhexyl ester and 2,4-D 2-ethylhexyl ester was made to barley at the combined maximum rate of approximately 732 g a.e./ha (252 g 2,4-DP-p a.e./ha and 480 g 2,4-D a.e./ha). The application was made using ground equipment.

Hay samples were collected at PHIs of 28 to 44 days and, straw and grain samples were collected at crop maturity (PHIs of 58 to 79 days). At the decline sites, hay samples were cut at PHIs of 1, 3, 7, 14, 28, 42 and 56 days and left to dry in the field before being collected. Straw and grain samples were collected at a PHI of 30 days and at normal crop maturity (PHIs of 56 and 79 days). The barley trials were conducted according to the Canadian GAP.

Commodity	Total Applic. Rate (g a.e./ha)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Dichlorprop-P									
Barley hay	~252	28-44	12	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Barley grain		58-79	12	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Barley straw		58-79	12	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0

2,4-D									
Barley hay	~480	28-44	12	<LOQ	0.81	0.70	0.36	0.41	0.18
Barley grain		58-79	12	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Barley straw		58-79	12	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0

In support of the end-use product OPTICA TRIO

Twelve field trials, including two decline trials, were conducted in Canada in barley during the 2006 and 2007 growing seasons in locations satisfying the PMRA registration requirements [1 trial in Zone 5, 1 trial in Zone 5B, 1 trial in Zone 7 and 9 trials in Zone 14].

At each test location, a single post-emergence foliar application of Optica Trio, a co-formulation containing DMA salts of 2,4-DP-p, MCPA and mecoprop-P, was made to barley at the combined maximum rate of approximately 1500 g a.e./ha (772 g 2,4-DP-p a.e./ha, 399 g MCPA a.e./ha and 329 g MCPP-p a.e./ha). The application was made using ground equipment.

Hay samples were collected at PHIs of 28 to 57 days and, straw and grain samples were collected at crop maturity (PHIs of 66 to 92 days). At the decline sites, hay samples were cut at PHIs of 1, 3, 7, 14, 28, 42 and 56 days and left to dry in the field before being collected. Straw and grain samples were collected at a PHI of 39 days and at normal crop maturity (PHI of 74 days). The barley trials were conducted according to the Canadian GAP.

Commodity	Total Applic. Rate (g a.e./ha)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Dichlorprop-P									
Barley hay	~772	28-57	24	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Barley grain		66-92	24	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Barley straw		66-92	24	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
MCPA									
Barley hay	~399	28-57	24	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Barley grain		66-92	24	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Barley straw		66-92	24	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
2-HMCPA									
Barley hay	(~399 for MCPA)	28-57	24	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Barley grain		66-92	24	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Barley straw		66-92	24	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Mecoprop-P									
Barley hay	~329	28-57	24	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Barley grain		66-92	24	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Barley straw		66-92	24	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0

CROP FIELD TRIALS AND RESIDUE DECLINE IN FIELD CORN	PMRA # 1461225, 1554766, 1753999 and 1754010

In support of the end-use product Estaprop XT Liquid Herbicide

Eight field trials, including one decline trial, were conducted in Canada in field corn during the 2005 and 2006 growing seasons in locations satisfying the PMRA registration requirements [6 trials in Zone 5 and 2 trials in Zone 5B].

At each test location, a single post-emergence foliar application of a co-formulation containing 2,4-DP-p 2-ethylhexyl ester and 2,4-D 2-ethylhexyl ester was made to field corn at the combined maximum rate of approximately 732 g a.e./ha (252 g 2,4-DP-p a.e./ha and 480 g 2,4-D a.e./ha). The application was made using ground equipment.

Forage samples were collected at PHIs of 75 to 98 days and, stover and grain samples were collected at crop maturity (PHIs of 114 to 147 days). At the decline site, forage samples were collected at PHIs of 0, 1, 3, 7, 14, 28, 45, 60 and 75 days. Stover and grain samples were collected at bulk layer (PHI of 105 days) and at normal crop maturity (PHI of 114 days). The field corn trials were conducted according to the Canadian GAP.

Commodity	Total Applic. Rate (g a.e./ha)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Dichlorprop-P									
Field Corn forage	~252	75-98	16	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Field Corn grain		114-147	16	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Field Corn stover		114-147	16	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
2,4-D									
Field Corn forage	~480	75-98	16	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Field Corn grain		114-147	16	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Field Corn stover		114-147	16	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0

In support of the end-use product OPTICA TRIO

Eight field trials, including one decline trial, were conducted in Canada in field corn during the 2006 and 2007 growing seasons in locations satisfying the PMRA registration requirements [6 trials in Zone 5 and 2 trials in Zone 5B].

At each test location, a single post-emergence foliar application of Optica Trio, a co-formulation containing DMA salts of 2,4-DP-p, MCPA and mecoprop-P, was made to field corn at the combined maximum rate of approximately 1500 g a.e./ha (772 g 2,4-DP-p a.e./ha, 399 g MCPA a.e./ha and 329 g MCPP-p a.e./ha). The application was made using ground equipment.

Forage samples were collected at PHIs of 75 to 107 days and, stover and grain samples were collected at crop maturity (PHIs of 113 to 143 days). At the decline site, forage samples were collected at PHIs of 0, 1, 3, 7, 14, 28, 45, 60 and 75 days. Stover and grain samples were collected at normal crop maturity and 15 days before and after maturity, corresponding to PHIs of 98, 113 (mature) and 128 days. The field corn trials were conducted according to the Canadian GAP.

Commodity	Total Applic. Rate (g a.e./ha)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Dichlorprop-P									
Field Corn forage	~772	75-107	16	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Field Corn grain		113-143	16	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Field Corn stover		113-143	16	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0

MCPA									
Field Corn forage	~399	75-107	16	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Field Corn grain		113-143	16	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Field Corn stover		113-143	16	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
2-HMCPA									
Field Corn forage	(~399 for MCPA)	75-107	16	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Field Corn grain		113-143	16	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Field Corn stover		113-143	16	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Mecoprop-P									
Field Corn forage	~329	75-107	16	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Field Corn grain		113-143	16	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
Field Corn stover		113-143	16	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	0
PROCESSED FOOD AND FEED - WHEAT							**PMRA # 1554767**		
To evaluate residues in wheat processing fractions, grain samples (control and treated) were collected from the 5X treated plot included in the wheat field trials. There were no residues of 2,4-DP-p and 2,4-D detected in the 5X grain samples. Therefore, since no residues above the LOQ (0.01 ppm) were found, the processing phase of the study was not conducted.									
LIVESTOCK FEEDING							**PMRA # 1284562**		
The registrant submitted a rationale to waive the requirement of livestock feeding study. Based on the fact that: - Dichlorprop-P residues in cereal matrices are close to or below the LOQ, even when treated at exaggerated rates. - In the rat and goat metabolism studies, dichlorprop-P is absorbed rapidly and excreted predominantly in urine within 24 hours of dosing. - Metabolism is minimal as the main excretion product is dichlorprop-P. - **Therefore, there is no expectation of finite residues in meat, milk and eggs and the livestock feeding studies can be waived.**									

Table 5 Food Residue Chemistry Overview of Metabolism Studies and Risk Assessment

PLANT STUDIES	
RESIDUE DEFINITION FOR ENFORCEMENT **Primary crops (corn)** **Rotational crops**	Dichlorprop Dichlorprop
RESIDUE DEFINITION FOR RISK ASSESSMENT **Primary crops** **Rotational crops**	Dichlorprop Dichlorprop
METABOLIC PROFILE IN DIVERSE CROPS	The profile in diverse crops cannot be determined, as only wheat was investigated.

ANIMAL STUDIES	
ANIMALS	**Ruminant**
RESIDUE DEFINITION FOR ENFORCEMENT	Dichlorprop
RESIDUE DEFINITION FOR RISK ASSESSMENT	Dichlorprop
METABOLIC PROFILE IN ANIMALS **(goat, hen, rat)**	Similar between rat and goat. Poultry was not investigated.
FAT SOLUBLE RESIDUE	No

DIETARY RISK FROM FOOD AND WATER			
	POPULATION	**ESTIMATED RISK % of ACCEPTABLE DAILY INTAKE (ADI)**	
		Food Only	**Food and Water**
Basic chronic non-cancer dietary risk **ADI = 0.07 mg/kg bw** **Estimated chronic drinking water concentration = 31 μg/L**	**All infants < 1 year**	0.3	3.3
	Children 1–2 years	0.8	2.2
	Children 3 to 5 years	0.6	1.9
	Children 6–12 years	0.4	1.3
	Youth 13–19 years	0.2	0.9
	Adults 20–49 years	0.2	1.0
	Adults 50+ years	0.1	1.1
	Female 13-49 years old	0.1	1.0
	Total population	0.2	1.2
	POPULATION	**ESTIMATED RISK % of ACUTE REFERENCE DOSE (ARfD)**	
		Food Only	**Food and Water**
Basic acute dietary exposure analysis, 95th percentile **ARfD = 0.07 mg/kg bw** **Estimated acute drinking water concentration = 118 μg/L**	**Children 1–2 years**	1.69	14.68
	Children 3 to 5 years	1.15	13.25
	Children 6–12 years	0.77	9.24
	Youth 13–19 years	0.45	7.42
	Adults 20–49 years	0.33	8.37
	Adults 50+ years	0.27	7.50
	Female 13-49 years old	0.32	8.38
	Total population	0.65	9.17

Table 6 Toxic Substances Management Policy (TSMP) Considerations-Comparison to Toxic Substances Management Policy

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Active Ingredient Endpoints	Transformation Products Endpoints
CEPA toxic or CEPA toxic equivalent[1]	Yes		yes	n/a
Predominantly anthropogenic[2]	Yes		yes	n/a
Persistence[3]:	Soil	Half-life $\geq$ 182 days	Half-life 16 days	n/a
	Water	Half-life $\geq$ 182 days	Half-life 15 days	n/a
	Sediment	Half-life $\geq$ 365 days	Half-life 408 days	n/a
	Air	Half-life $\geq$ 2 days or evidence of long range transport	Half-life or volatilisation is not an important route of dissipation and long-range atmospheric transport is unlikely to occur based on the vapour pressure (3.0E-04 Pa @ 25°C) and Henry's Law Constant (K = 1.565E-01 Pa (25°C) 1/H = 8.78 x 10^6)	n/a
Bioaccumulation[4]	Log $K_{OW} \geq 5$		-0.67	n/a
	BCF $\geq$ 5000		not available	n/a
	BAF $\geq$ 5000		not available	n/a
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			No, does not meet TSMP Track 1 criteria.	No major transformation products

[1] All pesticides will be considered CEPA-toxic or CEPA toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required.

[2] The policy considers a substance "predominantly anthropogenic" if, based on expert judgement, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.

[3] If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.

[4] Field data (exempli gratia, BAFs) are preferred over laboratory data (exempli gratia, BCFs) which, in turn, are preferred over chemical properties (exempli gratia, log K_{OW}).

Table 7 Fate and Behaviour in the Terrestrial Environment

Property	Test substance	Value	Transformation products	Classification	PMRA#
Abiotic transformation					
Phototransformation on soil	2,4-DP-p acid	*ca* 13 days	2,4-dichlorophenol	not expected to be an important route of transformation	1098619
Phototransformation in air	no data required as 2,4-DP-p is not expected to be volatile under field conditions				
Biotransformation					
Biotransformation in aerobic soil	2,4-DP-p acid	6.4 – 17.6 days	Major: CO_2 Minor: 2,4 dichlorophenol, 2,4-dichloroanisole	expected to be an important route of transformation	1098623

Property	Test substance	Value	Transformation products	Classification	PMRA#
Biotransformation in anaerobic water/sediment system	2,4-DP-p acid	>365 days	Major: CO_2 Minor: 2,4 dichlorophenol	supplemental study, significant variability between replicates	1098626
Mobility					
Adsorption / desorption in soil	2,4-DP-p acid	K_d = 0.23 - 1.82 K_{oc} = 30.1 - 88.3	-	highly to very highly mobile	1785751
Soil leaching	2,4-DP-p acid	Un-aged 0 – 6 cm layer: 5.2 - 7.8% AR Aged 0 – 6 cm layer: 28.6 – 50.4% AR	Major: CO_2 Minor: 2,4 dichlorophenol, 2,4-dichloroanisole	2,4-DP-p acid found (>10%AR) in leachate for aged and un-aged soils High mobility	1098628
Field studies					
Field dissipation	2,4-DP-p EHE	1.4 – 9.2 days, bare ground	Major: 2,4-DP-p acid; 2,4-DCP; 2,4-DCA	non-persistent	1094310
	2,4-DP-p DMA	2.6 days, bare ground 4.2 days; turf	Major: 2,4-DP-p acid	non-persistent	1094294

Table 8 Fate and Behaviour in the Aquatic Environment

Study type	Test material	Value	Transformation products	Classification	PMRA#
Abiotic transformation					
Hydrolysis	2,4-DP-p acid	stable	none	not expected to be an important route of transformation	1098616
Phototransformation in water	2,4-DP-p acid	$t_{1/2}$ = 4 days	Major: CO_2 Minor: 2,4-dichlorophenol	expected to be an important route of transformation	1098620
Biotransformation					
Biotransformation in aerobic water systems	2,4-DP-p acid	$t_{1/2}$ = 14 days	Major: CO_2 Minor: none	non-persistent expected to be an important route of transformation	1098625

Study type	Test material	Value	Transformation products	Classification	PMRA#
Biotransformation in anaerobic water systems	2,4-DP-p acid	$t_{1/2}$ =474 days	Major: CO_2 Minor: 2,4-dichlorophenol	persistent >6 months	1098626
Partitioning					
Adsorption / desorption in sediment	2,4-DP-p acid	K_d: 0.23 – 1.82 K_{oc}: 30.1-88.3	not reported	4 different soil types were used for adsorption/des study	1098627

Table 9 Parent and Minor Transformation Products (No Major Transformation Products were Reported)

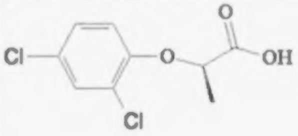
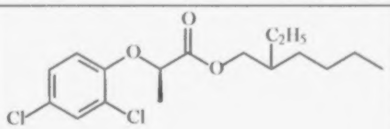
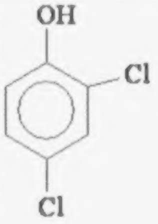
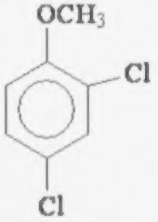
Chemical name [CAS]	Chemical Structure	Chemical Formula	Transformation Process
(+)-(R)-2-(2,4-Dichlorophenoxy) propanoic acid [15165-67-0] 2,4-DP-p acid		$C_9H_8Cl_2O_3$	n/a
(+)-(R)-2-(2,4-dichlorophenoxy) propanoic acid, 2-ethylhexyl ester [865363-39-9] 2,4-DP-p EHE		$C_{17}H_{24}Cl_2O_3$	n/a
2,4-dichlorophenol [120-83-2] **also an impurity in the synthesis of the TGAI**		$C_6H_4Cl_2O$	soil photolysis aerobic soil biotransformation anaerobic water sediment biotransformation terrestrial field dissipation also an impurity in the synthesis of 2,4-DP-p
2,4-dichloroanisole [553-82-2]		$C_7H_6Cl_2O$	aerobic soil biotransformation terrestrial field dissipation

Table 10 Effects on Terrestrial Organisms

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[a]	PMRA#
Invertebrates					
Earthworm	14d-Acute	2,4-DP-p acid	LC_{50}>1000 mg/kg soil		1288243
Honeybee	48h-Oral	2,4-DP-p EHE	202 kg ai.i/ha	relatatively non-toxic	1094314
	48h-Contact	2,4-DP-p EHE	199 kg a.i./ha		
Predatory arthropod	14 day-Contact	2,4-DP-p EHE	261 g a.i./ha		1094297
Parasitic arthropod	48h-Contact	2,4-DP-p EHE	521 g a.i./ha		1288249
Birds					
Bobwhite quail	14 d-Acute Oral	2,4-DP-p EHE	LD_{50}[a] =579 a.c. mg/kg b.w.	slightly toxic	1094302
	10 d-Acute Oral	2,4-DP-p DMA	LD_{50}[a] =242 a.c. mg /kg b.w.	moderately toxic	1089653
	8 d-Dietary	2,4-DP-p EHE	LC_{50}[a] =3921 a.c mg/ kg diet	slightly toxic	1094303
	10 d-Dietary	2,4-DP-p DMA	LC_{50}[a] =4858 a.c. mg/kg diet	slightly toxic	1288255
Mallard duck	8 d-Dietary	2,4-DP-p EHE	LC_{50}[a] >3921 a.c mg/kg diet	slightly toxic	1094304
	8 d Dietary	2,4-DP-p DMA	LC_{50}[a] >4858 a.c. mg/kg diet	slightly toxic	1288256
Japanese quail	One generation Reproduction (6 weeks exposure for each parents and off-spring)	2,4-DP-p DMA	NOAEC = 245 a.c. mg/ kg diet		1098656
Mammals					
Rat *Rattus norvegicus*	Acute oral	2,4-DP-p acid	♂♀ = 567 mg/kg bw (391-743)	slightly toxic	1097063
	Chronic (2 generation reproductive)	2,4-DP-p acid	NOAELs, mg/kg bw/d: ♂ = 40, ♀ = 42 LOAELs, mg/kg bw/d: ♂ = 207, ♀ = 218 (mean: 213)		1097038 1097076
Mouse	90d-Dietary	2,4-dichlorprop-P, 95.6%	NOAEL = 100 ppm ♂ = 20, ♀ = 33 mg/kg bw/d LOAEL = 1000 ppm ♂ = 224, ♀ = 380 mg/kg bw/d USEPA: NOAEL = 1000 ppm		1099527 1099552

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[a]	PMRA#
Rabbit	Chronic (2 generation reproductive)	2,4-dichlorprop-P, ≥94.5 %; 91-1	NOAEL: maternal and developmental toxicity = 50 mg/kg bw/d LOAEL: maternal and developmental toxicity = 100 mg/kg bw/d not teratogenic oral gavage on gestation days 7-19		1097041
Vascular plants					
Vascular plant	21 d-Seedling emergence	BAS 044 26 H (602 g a.i./L)	EC_{25}: 23.6 g/ha (onion)		1098664
	21 d-Vegetative vigour	2,4-DP-p acid	EC_{25}: 19 g/ha (cabbage)		1098662

Table 11 Effects on Aquatic Organisms

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[a]	PMRA#
Freshwater species					
Daphnia magna	48h-Acute	2,4-DP-p acid	LC_{50}>88 mg a.i./L	practically non-toxic	1098648
	22d-Chronic	2,4-DP-p acid	NOAEC = 103 mg a.i./L	practically non-toxic	1098649
Rainbow trout	96h-Acute	2,4-DP-p acid	LC_{50}>216 mg a.i./L	practically non-toxic	1098650
green algae (*Selenastrum capricornutum*)	72h-Acute	2,4-DP-p acid	EC_{50}>94 mg a.i./L		1098657
freshwater blue-green alga (*Anabaena flos-aquae*)	72h-Acute	2,4-DP-p acid	EC_{50} = 20 mg a.i./L		1098658
freshwater diatom (*Navicula pelliculosa*)	72h-Acute	2,4-DP-p acid K+ salt	EC_{50}>101 mg a.i./L		1098659
Vascular plant (*Lemna gibba*)	7d-Over-spray	2,4-DP-p acid K+ salt	EC_{50} = 32 mg a.i./L		1098665
Marine species					
Marine diatom *Skeletonema costatum*	96h-Acute	2,4-DP-p DMA	EC_{50} = 249 mg a.e./L NOEC = 63 mg a.e./L		1098660

Table 12 Screening Level Risk Assessment on Non-target Species

Organism	Exposure	Endpoint value	EEC (Soil: mg a.i./kg; Direct overspray: g a.i./ha)	RQ	Risk
Invertebrates					
Earthworm	Acute	LC_{50}>1000 mg/kg soil	1.12 kg a.i./ha	0.001	no
Bee	Oral	LC_{50}=202 kg a.i./ha	2.5 kg a.i./ha	0.012	no
	Contact	LC_{50}=	2.5 kg a.i./ha	0.013	no
Predatory arthropod	Contact	LR_{50}=261 g a.i./ha	1260 g a.i./ha (on-field)	4.83	yes
Predatory arthropod	Contact	LR_{50}=261 g a.i./ha	252 g a.i./ha (off-field)	0.97	no
Parasitic arthropod	Contact	LR_{50}=521 g a.i./ha	1260 g a.i./ha (on-field)	2.42	yes
Parasitic arthropod	Contact	LR_{50}=521 g a.i./ha	252 g a.i./ha (off-field)	0.0005	no
Vascular plants					
Vascular plant	Seedling emergence	EC_{25}: 23.6 g/ha (onion)	2520 g a.i./ha	106.78	yes
	Vegetative vigour	EC_{25}: 19 g/ha (cabbage)	2520 g a.i./ha	132.63	yes

Table 13 Refined Risk Assessment on Non-Target Species (2,4-DP-p: 1500 g a.i./ha, using mean residues)

Toxicity endpoint (mg a.i./kg bw/d)		Food Guild	EDE^1 (mg a.i./kg bw)	RQ^2	Exceeds LOC^3
Small Bird (0.02 kg)					
Acute	24.2	Insectivore (small insects)	21.8	1.7	yes
	24.2	Granivore (grain and seeds)	4.7	0.4	no
	24.2	Frugivore (fruit)	9.3	0.7	no
Dietary	22.2	Insectivore (small insects)	21.8	1.9	yes
	22.2	Granivore (grain and seeds)	4.7	0.4	no
	22.2	Frugivore (fruit)	9.3	0.8	no
Reproduction	76.1	Insectivore (small insects)	21.8	0.6	no
	76.1	Granivore (grain and seeds)	4.7	0.1	no
	76.1	Frugivore (fruit)	9.3	0.2	no
Medium Sized Bird (0.1 kg)					
Acute	24.2	Insectivore (small insects)	17.0	1.4	yes
	24.2	Insectivore (large insects)	3.6	0.3	no
	24.2	Granivore	3.6	0.3	no

Toxicity endpoint (mg a.i./kg bw/d)		Food Guild	EDE[1] (mg a.i./kg bw)	RQ[2]	Exceeds LOC[3]
		(grain and seeds)			
	24.2	Frugivore (fruit)	7.3	0.6	no
Dietary	22.2	Insectivore (small insects)	17.0	1.5	yes
	22.2	Insectivore (large insects)	3.6	0.3	no
	22.2	Granivore (grain and seeds)	3.6	0.3	no
	22.2	Frugivore (fruit)	7.3	0.6	no
Reproduction	76.1	Insectivore (small insects)	17.0	0.4	no
	76.1	Insectivore (large insects)	3.6	0.1	no
	76.1	Granivore (grain and seeds)	3.6	0.1	no
	76.1	Frugivore (fruit)	7.3	0.2	no
Large Sized Bird (1 kg)					
Acute	24.2	Insectivore (small insects)	5.0	0.4	no
	24.2	Insectivore (large insects)	1.1	0.1	no
	24.2	Granivore (grain and seeds)	1.1	0.1	no
	24.2	Frugivore (fruit)	2.1	0.2	no
	24.2	Herbivore (short grass)	11.3	0.9	no
	24.2	Herbivore (long grass)	6.3	0.5	no
	24.2	Herbivore (forage crops)	9.7	0.8	no
	24.2	Herbivore (leafy foliage)	19.8	1.6	yes
Dietary	22.2	Insectivore (small insects)	5.0	0.4	no
	22.2	Insectivore (large insects)	1.1	0.1	no
	22.2	Granivore (grain and seeds)	1.1	0.1	no
	22.2	Frugivore (fruit)	2.1	0.2	no
	22.2	Herbivore (short grass)	11.3	1.0	yes
	22.2	Herbivore (long grass)	6.3	0.6	no
	22.2	Herbivore (forage crops)	9.7	0.8	no
	22.2	Herbivore (leafy foliage)	19.8	1.7	no
Reproduction	76.1	Insectivore (small insects)	5.0	0.1	no
	76.1	Insectivore (large insects)	1.1	0.0	no

Toxicity endpoint (mg a.i./kg bw/d)		Food Guild	EDE[1] (mg a.i./kg bw)	RQ[2]	Exceeds LOC[3]
	76.1	Granivore (grain and seeds)	1.1	0.0	no
	76.1	Frugivore (fruit)	2.1	0.1	no
	76.1	Herbivore (short grass)	11.3	0.3	no
	76.1	Herbivore (long grass)	6.3	0.2	no
	76.1	Herbivore (forage crops)	9.7	0.2	no
	76.1	Herbivore (leafy foliage)	19.8	0.5	no

1Estimated Daily Exposure (EDE) = FIRww/bw*EEC
Estimated Environmental Concentration (EEC) in fresh diet (mg a.i./kg fresh weight diet)
Food Ingestion Rate of indicator species in wet weight (FIR)
Bodyweight (bw) (kg);
2Risk Quotient (RQ) = exposure/toxicity
3Level of Concern (LOC)
Shaded cells indicate that the RQ exceeds the LOC, triggering a refined risk assessment and further characterization where possible.

Toxicity endpoint (mg a.i./kg bw/d)		Food Guild	EDE[1] (mg a.i./kg bw)	RQ[2]	Exceeds LOC[3]
Small Mammal (0.015 kg)					
Acute	56.7	Insectivore (small insects)	12.5	0.2	no
	56.7	Granivore (grain and seeds)	2.7	0.0	no
	56.7	Frugivore (fruit)	5.4	0.1	no
Reproduction	41.0	Insectivore (small insects)	12.5	0.3	no
	41.0	Granivore (grain and seeds)	2.7	0.1	no
	41.0	Frugivore (fruit)	5.4	0.1	no
Medium Sized Mammal (0.035 kg)					
Acute	56.7	Insectivore (small insects)	11.0	0.2	no
	56.7	Insectivore (large insects)	2.3	0.0	no
	56.7	Granivore (grain and seeds)	2.3	0.0	no
	56.7	Frugivore (fruit)	4.7	0.1	no
	56.7	Herbivore (short grass)	25.0	0.4	no
	56.7	Herbivore (long grass)	14.0	0.2	no
	56.7	Herbivore (forage crops)	21.5	0.4	no
	56.7	Herbivore (leafy foliage)	43.8	0.8	no
Reproduction	41.0	Insectivore (small insects)	11.0	0.3	no
	41.0	Insectivore (large insects)	2.3	0.1	no
	41.0	Granivore (grain and seeds)	2.3	0.1	no
	41.0	Frugivore (fruit)	4.7	0.1	no
	41.0	Herbivore (short grass)	25.0	0.6	no
	41.0	Herbivore (long grass)	14.0	0.3	no
	41.0	Herbivore (forage crops)	21.5	0.5	no
	41.0	Herbivore (leafy foliage)	43.8	1.1	yes
Large Sized Mammal (1 kg)					
Acute	56.7	Insectivore (small insects)	5.9	0.1	no
	56.7	Insectivore (large insects)	1.3	0.0	no
	56.7	Granivore (grain and seeds)	1.3	0.0	no

Toxicity endpoint (mg a.i./kg bw/d)		Food Guild	EDE[1] (mg a.i./kg bw)	RQ[2]	Exceeds LOC[3]
	56.7	Frugivore (fruit)	2.5	0.0	no
	56.7	Herbivore (short grass)	13.4	0.2	no
	56.7	Herbivore (long grass)	7.5	0.1	no
	56.7	Herbivore (forage crops)	11.5	0.2	no
	56.7	Herbivore (leafy foliage)	23.4	0.4	no
Reproduction	41.0	Insectivore (small insects)	5.9	0.1	no
	41.0	Insectivore (large insects)	1.3	0.0	no
	41.0	Granivore (grain and seeds)	1.3	0.0	no
	41.0	Frugivore (fruit)	2.5	0.1	no
	41.0	Herbivore (short grass)	13.4	0.3	no
	41.0	Herbivore (long grass)	7.5	0.2	no
	41.0	Herbivore (forage crops)	11.5	0.3	no
	41.0	Herbivore (leafy foliage)	23.4	0.6	no

[1] Estimated Daily Exposure (EDE) = FIRww/bw*EEC
Estimated Environmental Concentration (EEC) in fresh diet (mg a.i./kg fresh weight diet)
Food Ingestion Rate of indicator species in wet weight (FIR)
Bodyweight (bw) (kg);
[2] Risk Quotient (RQ) = exposure/toxicity
[3] Level of Concern (LOC)
Shaded cells indicate that the RQ exceeds the LOC, triggering a refined risk assessment and further characterization where possible.

Table 14 Screening Level Risk Assessment for Aquatic Organisms

Organism	Exposure	Endpoint value (mg a.i./L)	EEC[1] (mg a.i./L)	RQ[2]	Exceeds LOC[3]
Freshwater species					
Daphnia magna	Acute	LC_{50}>88/2 = 44	0.315	0.007	no
	Chronic	NOAEC=103	0.315	0.003	no
Rainbow trout	Acute	LC_{50}>216/10 = 21.6	0.315	0.015	no
Amphibians[4]	Acute	LC_{50}>216 /10=21.6	1.68	0.078	no
Freshwater algae					
green algae (*Selenastrum capricornutum*)	Acute	EC_{50}>94/2 = 47	0.315	0.007	no
freshwater blue-green alga (*Anabaena flos-aquae*)	Acute	EC_{50}>20/2 = 10	0.315	0.032	no
freshwater diatom (*Navicula pelliculosa*)	Acute	EC_{50}>101/2=51	0.315	0.006	no
Vascular plant (*lemna gibba*)	Static renewal	EC_{50}>32 /2=16	0.315	0.020	no
Marine species					
Marine diatom *Skeletonema costatum*	96 hour	EC_{50}=249/2=125	0.315	0.003	no

[1] Estimated Environmental Concentration (EEC) on in water.
[2] Risk Quotient (RQ) = exposure/toxicity. For fish, RQ = EEC in an 80-cm deep water body / (EC_{50} ÷ 10 or LC_{50} ÷ 10); for a chronic exposure: RQ = EEC in an 80-cm deep water body / NOEC; for amphibians, the EEC in a 15 cm-deep water body is used. For aquatic invertebrates and plants, RQ = EEC in a 80-cm deep water body / (EC_{50} ÷ 2 or LC_{50} ÷ 2); for a chronic exposure: RQ = EEC in a 80-cm deep water body / NOEC

Organism	**Exposure**	**Endpoint value (mg a.i./L)**	**EEC[1] (mg a.i./L)**	**RQ[2]**	**Exceeds LOC[3]**
[3] Level of Concern (LOC) [4] the endpoint values for the most sensitive fish species at the appropriate exposure scenario were used as surrogate data for the amphibian risk assessment.					

Table 15 Scenario Specific Exposures and Risk to 2, 4-DP-P

M/L/A Scenario	**Application Rate kg a.i./ha/L**	**Area Treated per Day (ha, or L)[1]**	**Dermal Unit exposure (µg/kg ai)[2]**	**Dermal Exposure (µg/kg bw/day)[3]**	**Inhalation Unit exposure (µg/kg ai)[2]**	**Inhalation Exposure (µg/kg bw/day)[4]**	**Dermal MOE[5] Target MOE 100**	**Inhalation MOE[6] Target MOE100**
Estaprop XT liquid Herbicide								
USC 13,14: Spring Cereals (wheat and barley) and winter wheat								
Liquid open pour mix, load (Scenario 3a) wearing long sleeved shirt, long pants and CR gloves + ground boom open cab application, no gloves (Scenario 11).	0.252	Farmer 107	84.12	0.03240	2.56	0.00099	30860	7100
Liquid open pour mix, load (Scenario 3a) wearing long sleeved shirt, long pants and CR gloves + ground boom open cab application, no gloves (Scenario 11).	0.252	Custom 360	84.12	0.10902	2.56	0.00332	9170	2110
Liquid; open pour mix/load (Scenario 3a), Coveralls over long sleeved shirt, long pants and CR gloves, for aerial application	0.252	400	32.77	0.04719	1.60	0.00230	21190	3040
Aerial (Fixed-wing and rotary wing) liquid application, (Scenario 7a), with a long sleeved shirt and long pants and no gloves	0.252	400	9.66	0.01391	0.07	0.00010	71890	70000
USC 16: Industrial and Non cropland, annual and perennial weed control at low rate by ground or aerial								
Open pour mix/load (Scenario 3a) + Right of way sprayer (Scenario 18)	0.588	3800L	923.68	0.02998	6.60	0.00021	33920	33300
Low Pressure Hand wand M/L/A (Scenario 21a, with a long sleeved shirt and long pants and CR gloves	0.588	150L	943.37	0.00119	45.20	0.00006	840300	116660
High Pressure Hand wand M/L/A (Scenario 24a, with a long sleeved shirt and long pants and CR gloves	0.588	3800L	5585.49	0.17829	151	0.00482	5610	1450

M/L/A Scenario	**Application Rate kg a.i./ha/L**	**Area Treated per Day (ha, or L)[1]**	**Dermal Unit exposure (µg/kg ai)[2]**	**Dermal Exposure (µg/kg bw/day)[3]**	**Inhalation Unit exposure (µg/kg ai)[2]**	**Inhalation Exposure (µg/kg bw/day)[4]**	**Dermal MOE[5] Target MOE 100**	**Inhalation MOE[6] Target MOE100**
Liquid Open Pour, M/L/A. Backpack, with a long sleeved shirt, long pants and CR gloves	0.588	150L	5445.85	0.00686	62.10	0.00008	145770	87500
Liquid open pour mix, load (Scenario 3a) wearing long sleeved shirt, long pants and CR gloves + ground boom open cab application, no gloves (Scenario 11).	0.588	Custom: 360	84.12	0.25438	2.56	0.00774	3930	900
Liquid; open pour mix/load (Scenario 3a), Coveralls over long sleeved shirt, long pants and CR gloves, for aerial application	0.588	400	32.77	0.11011	1.60	0.00538	9080	1300
Aerial (Fixed-wing and rotary wing) liquid application, (Scenario 7a), long sleeved shirt and long pants, no gloves	0.588	400	9.66	0.03246	0.07	0.00024	30800	29170
USC 16: Industrial and Non cropland, for brush control at high rate as a spot treatment								
Open pour mix/load (Scenario 3a) + Right of way sprayer (Scenario 18) wearing a long sleeved shirt, long pants and CR gloves	0.00252	3800L	923.68	0.12636	6.60	0.00090	7910	7780
Low Pressure Hand wand M/L/A (Scenario 21a, wearing a long sleeved shirt and long pants and CR gloves	0.00252	150L	943.37	0.00509	45.20	0.00024	198020	29170
High Pressure Hand wand M/L/A (Scenario 24a, wearing a long sleeved shirt , long pants and CR gloves	0.00252	3800L	5585.49	0.76410	151	0.02066	1310	340
Liquid Open Pour, M/L/A. Backpack, wearing a long sleeved shirt and long pants and CR gloves	0.00252	150L	5445.85	0.02940	62.10	0.00034	34000	20590

M/L/A Scenario	Application Rate kg a.i./ha/L	Area Treated per Day (ha, or L)[1]	Dermal Unit exposure (µg/kg ai)[2]	Dermal Exposure (µg/kg bw/day)[3]	Inhalation Unit exposure (µg/kg ai)[2]	Inhalation Exposure (µg/kg bw/day)[4]	Dermal MOE[5] Target MOE 100	Inhalation MOE[6] Target MOE100
Brush control by aerial method for a tank mix with Vanquish herbicide								
Liquid; open pour mix/load (Scenario 3a), Coveralls over long sleeved shirt, long pants and CR gloves, for aerial application	1.76	400	32.77	0.32957	1.60	0.0161	3030	440
Aerial (Fixed-wing and rotary wing) liquid application, (Scenario 7a), wearing a long sleeved shirt and long pants and no gloves	1.76	400	9.66	0.09715	0.07	0.0007	10300	10000
USC 16: Industrial and Non cropland, Brush control by Basal treatments								
Basal treatment								
Liquid Open Pour, M/L/A. Backpack, wearing a long sleeved shirt and long pants and CR gloves	0.00462	150L	5445.85	0.05391	62.10	0.000615	18550	11390
Low Pressure Hand wand M/L/A (Scenario 21a, wearing a long sleeved shirt and long pants and CR gloves	0.00462	150L	943.37	0.00934	45.20	0.00045	107070	15560
Modified basal treatment								
Liquid Open Pour, M/L/A. Backpack, wearing a long sleeved shirt and long pants and CR gloves	0.00174	150L	5445.85	0.02034	62.10	0.000232	49160	30180
Low Pressure Hand wand M/L/A (Scenario 21a, wearing a long sleeved shirt and long pants and CR gloves	0.00174	150L	943.37	0.00352	45.20	0.00017	284100	41200
Cut surface frill treatment								
Liquid Open Pour, M/L/A. Backpack, wearing a long sleeved shirt and long pants and CR gloves	0.00472	150L	5445.85	0.05485	62.10	0.00063	18230	11100
Low Pressure Hand wand M/L/A (Scenario 21a, wearing a long sleeved shirt and long pants and CR gloves	0.00472	150L	943.37	0.00950	45.20	0.00046	105260	15220

M/L/A Scenario	Application Rate kg a.i./ha/L	Area Treated per Day (ha, or L)[1]	Dermal Unit exposure (µg/kg ai)[2]	Dermal Exposure (µg/kg bw/day)[3]	Inhalation Unit exposure (µg/kg ai)[2]	Inhalation Exposure (µg/kg bw/day)[4]	Dermal MOE[5] Target MOE 100	Inhalation MOE[6] Target MOE100
Optica Trio								
USC 13,14: Cereals (Spring and Winter wheat, Barley and Oats)								
Liquid open pour mix, load (Scenario 3a) wearing long sleeved shirt, long pants and CR gloves + ground boom open cab application, no gloves (Scenario 11).	0.775	Farmer 107	84.12	0.09965	2.56	0.00303	10035	2310
Liquid open pour mix, load (Scenario 3a) wearing long sleeved shirt, long pants and CR gloves + ground boom open cab application, no gloves (Scenario 11).	0.775	Custom 360	84.12	0.33528	2.56	0.01020	2980	690

[1] Area treated per day as listed on the PMRA, Area Treated per Day Table, Revised Version-2.1, 20 July 2010).

[2] Dermal/Inhalation Unit exposures from PHED, Table 2

[3] Daily Dermal exposure (mg/kg bw/day) = (area treated per day x application rate) x dermal unit exposure x 100% dermal absorption x 0.001 mg/µg/70 kg bw

[4] Daily Inhalation exposure (mg/kg bw/day) = (area treated per day x application rate) x inhalation unit exposure x 100% inhalation exposure x 0.001mg/µg/70kgbw

[5] Dermal MOE = NOAEL of 1000 mg/kg bw/d /Dermal Exposure (mg/kg bw/day); Target MOE 100

[6] Inhalation MOE = NOAEL of 7 mg/kg bw/d /Inhalation exposure (mg/kg bw/day); Target 100

Table 16 Postapplication Exposure and Risk to 2, 4-DP-P

2,4-DP-P EP	Crop	Re-entry Activities	DFR[1] μg/cm^2	TC[2] cm^2/hr	Dermal Exposure[3,4] (μg/kg bw/day)	Dermal MOE[5] Target: 100
Estaprop XT Liquid Herbicide	Wheat Barley	Scouting Irrigation	0.50	1500	0.0867	11670
Estaprop XT Liquid Herbicide	Industrial Non-crop land, Low rate	Walking/ scouting non-crop/ industrial areas	1.18	500	0.0337	29670
Estaprop XT Liquid Herbicide	Industrial High rate	Walking/ scouting non-crop/ industrial areas	5.04	500	0.144	6940
Optica Trio	Wheat, barley, Oat	Scouting Irrigation	1.55	1500	0.2657	3800

[1] DFR = 20% of application rate of 2.52 μg/cm^2 (252 g a.i./ha) for cereals; 5.88 μg/cm^2 (588 g a.i./ha) for industrial weed control and 25.2 μg/cm^2 (2520 g a.i./ha) for industrial brush control (Estaprop XT Liquid Herbicide) and 20% of application rate of 7.75 μg/cm^2 (775 g a.i./ha) for cereals for Optica Trio.

[2] TC as documented in USEPA Science Advisory Council for Exposure, Policy number 003.1, 7 May 1998, revised 7 August 2000. TC for Industrial, non-crop land uses from 2, 4-D PACR2007-06.

[3] Duration of work day was assumed as 8hrs for cereal crops and 4 hrs/day for workers scouting on industrial land as workers would be spending most of the day in the car travelling to sites, or driving in the sites, with spot-scouting (2, 4-D PACR2007-06).

[4] Dermal Exposure (mg/kg bw/day) = [DFR (μg/cm^2)* TC* hrs* 100% dermal absorption)/ [body weight of 70 kg *1000 (μg/mg)].

[5] MOE = Dermal NOAEL of 1000 mg/kg bw/day ÷ Exposure (mg/kg bw/day); Target MOE 100.

Appendix II Supplemental Maximum Residue Limit Information—International Situation and Trade Implications

The Canadian MRLs differ from the tolerance established in the United States (40 CFR Part 180) and the Codex MRLs (Codex MRLs)

Table 1 Differences Between Canadian MRLs and in Other Jurisdictions

Commodity	Canada (ppm)	UNITED STATES (ppm)	Codex* (ppm)
Crop Group 15 (Cereal grains)	0.02	No MRL established in the United States	"Not reviewed by Codex"
Milk	0.01		
Eggs; Fat and Meat of cattle, goats, hogs, horses, poultry and sheep	0.02		
Meat by-products of cattle, goats, hogs, horses, poultry and sheep	0.05		

* Codex is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data. For animal commodities, differences in MRLs can be due to different livestock feed items and practices.

Under the North American Free Trade Agreement (NAFTA), Canada, the United States and Mexico are committed to resolving MRL discrepancies to the broadest extent possible. Harmonization will standardize the protection of human health across North America and promote the free trade of safe food products. Until harmonization is achieved, the Canadian MRLs specified in this document are necessary. The differences in MRLs outlined above are not expected to impact businesses negatively or adversely affect international competitiveness of Canadian firms or to negatively affect any regions of Canada.

Appendix III Monitoring Data

Water Monitoring Data

Data from Canadian and United States water monitoring studies in which dichlorprop was quantified are summarized in Appendix III, Table 1.
For purposes of the drinking water assessment, information was extracted from the available sources, tabulated and sorted into categories as follows:

Residues in known drinking water sources (both surface and groundwater)
Residues in ambient water that may serve as a drinking water source (both surface and groundwater)
Residues in ambient water that are unlikely to serve as a drinking water source

An important limitation of the monitoring data set is that, in many cases, the data were not accompanied with use data for dichlorprop. For instance, the application rate applied, when the application occurred and weather conditions prior to sampling were not known or reported. Without this information, it is difficult to conclude if non-detects were a result of non-transport or more simply a result of inappropriate timing of sampling. In addition, because the data are sparse and concentrations vary in time and space, the maximum concentration reported is unlikely to be the absolute maximum concentration that would be observed in Canada. Factors that may result in higher concentrations being detected include application at higher rates, precipitation and some areas/soils are simply more prone to leaching and/or run off. Sampling at intervals immediately following application would increase the likelihood that the maximum concentration would be detected.

Thus, it is likely dichlorprop was not used in some of the areas monitored, and that higher concentrations of dichlorprop may occur in other areas not monitored. The dichlorprop monitoring data likely underestimate the peak exposure because of the following limitations:

1. In general, the data are sparse in both time and location. In some of the studies available, dichlorprop was analyzed in samples that were taken from non-dichlorprop use areas. Dichlorprop use information from the areas surrounding where the samples were collected is often not available.

2. Sampling in some of the studies was conducted during periods when dichlorprop is not applied in Canada (i.e., October through March).

3. The concentrations of chlorophenoxy pesticides in surface water are directly related to the frequency and timing of monitoring in relation to pesticide application and runoff events. Therefore, timing and frequency of sampling is likely to be the most important factor influencing the concentration detected and the frequency of detections. Samples are often taken at arbitrary time intervals (i.e., once a month, once a week) and are unlikely to capture the absolute maximum concentration of dichlorprop.

The following statistics are used to interpret the information available in each dataset and are summarized in Appendix III, Table 1.

The detection frequency provides an indication of how often positive detections occur within the given data set. Detection frequency is primarily determined by the limits of detection and is influenced by pesticide use patterns and application rates. Consequently, a wide range of detection frequencies is likely to be expected.

The 95th percentile concentration is calculated and reported. Maximum values should also be considered, especially when the 95th percentile is not available which occurs when there are insufficient detections to calculate a 95th percentile.

The maximum concentration is reported and is used to determine the 95th percentile concentration to estimate an acute exposure value.

The arithmetic mean with non-detects considered at ½ LOD is used to determine the 95th percentile concentration to estimate a chronic exposure value.

Table 1: Summary of the monitoring studies available for dichlorprop-P

Data Source	**DETECTION FREQUENCY**						**CONCENTRATIONS (µg/L)**			
	Location		**Min detection or detection limit (µg/L)**	**# of systems tested (or absolute number of samples)**	**# of systems or samples with detections**	**Detection frequency (%)**	**Mean detection**	**95th**	**Absolute Max**	**Arithmetic Mean Including non-detects at ½ LOD**
Dichlorprop residues in municipal drinking water sources and groundwater										
PMRA 1403269, 1311107	Alberta drinking water reservoirs and tap water (2003- 2005)	Castor	0.00042	25	8	32	0.001495	0.0028	0.00318	0.000596
		Hay Lakes	0.00042	9	4	44.4	0.00227	0.0034	0.00365	0.00113
		Mirror	0.00042	11	5	45.5	0.00129	0.0019	0.00197	0.0007
		Picture Butte	0.00042	11	8	72.7	0.0052	0.0086	0.0092	0.0039
		Reservoir Water	0.00042	10	8	80	0.0067	0.023	0.03	0.0054
		Tap Water	0.00042	10	6	60	0.0056	0.0128	0.014	0.0034
PMRA 1857399	Finished water, US (2001)		0.0053	92	0	0	-	-	-	0.00265
PMRA 1857396	Finished water, US (2002)		0.0042	209	0	0	-	-	-	0.0021
PMRA 1857388	Finished drinking water, US (2003)		0.0042 - 0.006	281	0	0	-	-	-	0.003
PMRA 1852618	Untreated water, US (2005)		0.0018	118	5	4.2	-	-	0.011	0.0009

	Finished water, US (2005)		0.0018	119	5	4.2	-	-	0.003	0.0009
PMRA 1852614	Groundwater, US (2008)		-	250 samples from 136 wells	0	0	-	-	-	-
	Untreated water, US (2008)		0.0017-0.0018	308	5	1.6	-	-	0.019	0.0009
	Finished water, US (2008)		0.0017-0.0018	309	5	1.6	-	-	0.013	0.0009
Dichlorprop residues in ambient water that may serve as a drinking water source										
PMRA 1345581 & 1526788	Southern Manitoba Rivers - Red River and tributaries	Assiniboine River	0.000007	32	N/A	52	-	-	0.01241	0.0000035
		Lasalle River	0.000007	32	N/A	48	-	-	0.0105	0.0000035
		Morris River	0.000007	31	N/A	63	-	-	0.0175	0.0000035
		Pembina River	0.000007	31	N/A	44	-	-	0.00321	0.0000035
		Rat River	0.000007	32	N/A	38	-	-	0.00289	0.0000035
		Roseau River	0.000007	32	N/A	16	-	-	0.00053	0.0000035
		Seine River	0.000007	32	N/A	50	-	-	0.0196	0.0000035
		Red River at Emerson	0.000007	31	N/A	32	-	-	0.00381	0.0000035
		Red River at Ste. Agathe	0.000007	32	N/A	31	-	-	0.0022	0.0000035
		Red River at Selkirk	0.000007	33	N/A	52	-	-	0.0161	0.0000035
PMRA 1311111& 1403269	Pacific Yukon Region (PYR) (2003-2005)	Lower Fraser Valley (Runoff)	0.01	-	-	-	-	-	-	0.005
		Okanagan	N/A	-	-	-	-	-	-	-
	Priaries and Northern Region (PNR) (2003-2005)	Selected Canadian Prairie Aquatic Ecosystems	N/A	-	-	-	0.118	-	-	-
PMRA 1307580 & 1523030	Grand River (1981- 1985)		0.1	103	1	1	0.2	-	-	0.05
	Saugeen River (1981 - 1985)		0.1	140	1	0.7	0.2	-	-	0.05
	Thames River (1981- 1985)		0.1	204	16	7.8	0.5	-	-	0.05
PMRA 1307573	Surface water in Manitoba (1972-1994)	Manitoba Environment	0.1	696	26	3.7	-	-	0.61	0.05

		Environment Canada	0.03	1,580	41	2.6	-	-	0.9	0.015
PMRA 1311118	Alberta Surface waters (1995 2002)		0.005	3058	162	5.3	-	-	0.657	0.0025
PMRA 1311140	Storm drains and tributaries to the Oldman River in Lethbridge, Alberta (2000)		0.005	39	7	18	0.032	0.071	0.073	0.0078
PMRA 1345576	Elk Creek watershed and Yorkson Creek watershed in Lower Fraser Valley, British Columbia (1999-2001)		0.01-0.1	N/A	0	0	-	-	-	-
PMRA 1311133 & 1311134	Red River Flood in Southern Lake Winnipeg (1997)	Floodway	0.0001	13	1	7.7	-	-	0.00243	0.00005
		Selkirk	0.0001	21	4	19.1	0.0035	0.0055	0.00592	0.00005
		North and South Basins of Lake Winnipeg	0.0001	10	6	60	0.0039	0.0059	0.0062	0.00005
Dichlorprop residues in water that is unlikely to be used as a drinking water source (not used in the drinking water assessment)										
PMRA 1307555	Eight urban streams in diverse areas of U.S. (1993-1994)		N/A	-	-	1	-	-	0.19	-
PMRA 1307552	Saskatchewan wetlands with catchments areas within wildlife habitat, farms with moderate and intense herbicide use (1996-1998)	Wildlife habitat with no pesticide use	0.01	7	N/A	86	0.019	-	0.03	0.005
		Farms with no pesticide use	0.01	14	N/A	79	0.036	-	0.1	0.005
		Farms with conventional tillage	0.01	15	N/A	80	0.022	-	0.085	0.005
		Farms with minimum tillage	0.01	27	N/A	96	0.05		0.75	0.005
PMRA 1307553	Saskatchewan wetlands (1991-1994,1996)		0.03	32	N/A	N/A	-	-	1.59	0.015
PMRA 1311150, 1311151	Nose Creek watershed (1999)		0.005	20	5	25	-	-	0.025	0.0025
PMRA 1403269 , 1311116	Alberta	Stettler Wetland	0.00042	20	10	50	0.006	0.0145	0.02	0.0032
		Vegreville Wetland	0.00042	20	9	45	0.002	0.00248	0.00256	0.001

	Saskatchewan	Assiniboia Pasture Wetland	0.00042	20	9	45	0.0339	0.064	0.079	0.0153
		Assiniboia Crop Wetland		18	11	61	0.0472	0.0685	0.075	0.0263
	Manitoba	North Battleford Wetland		12	4	33.3	0.005	0.009	0.0095	0.0019
		Cardale Pond	0.00042	20	10	50	0.0124	0.0169	0.0183	0.0063

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

Dichlorporp-P

PMRA Document Number	Reference
1093668	2000, Section 2.1-2.9. Marks DP-p Technical Acid. Manufacturer and Product Identity, DACO: 2.1,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9 CBI
1093669	2000, Section 2.11. Marks DP-p Technical Acid. Manufacturing Methods for Technical Active Ingredient, DACO: 2.11 CBI
1093670	2000, Marks DP-p Technical Acid. Sections 2.12 and 2.13. Specifications/Quality Control/Analysis, DACO: 2.12,2.13 CBI
1093671	2000, Marks DP-p Technical Acid. Section 2.14. Chemical and Physical Properties, DACO: 2.14 CBI
1288143	2005, Sections 2.1-2.9, DACO: 2.1,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9
1288145	2005, Section 2.11, DACO: 2.11.1,2.11.2,2.11.3,2.11.4 CBI
1288146	2005, Section 2.11 appendix I, II, III, DACO: 2.11.1,2.11.2,2.11.3,2.11.4
1288147	2005, Section 2.12 and 2.13, DACO: 2.12,2.12.1,2.13.1,2.13.2,2.13.3 CBI
1288148	2005, Section 2.13.3 Appendix I- VII, DACO: 2.13.2,2.13.3 CBI
1098612	2001, Development and Validation of an Analytical Method for the Determination of Mecoprop-P (MCPP-P) and Dichlorprop-P (2,4-DP-P) in Soil, DACO: 8.2.2.1,8.2.2.2
1098614	2000, Analtical Methodology-Water, DACO: 8.2.2.3
1098615	1996, Analytical Methodology-Biota, DACO: 8.2.2.4
1288233	2006, 2,4-DP-p Task Force Waiver Request - Analytical Methodology (Parent Compound and Transformation Products) Waiver Request, DACO: 8.2.2
1288234	1994, Analytical Method for the Determination of Dichlorprop-P (2,4-DP-p); 2,4 Dichlorophenol (2,4-DCP); 2,4-Dichloroanisole (2,4-DCA); and 2,4-DP-p 2-EHE (2-EHE) in Soil, DACO: 8.2.2
1288235	1997, Independent Laboratory Method Trials of a Residue Analytical Method for Dichlorprop-P (2,4-DP-p) and Metabolites in Soil, DACO: 8.2.2
1288236	1993, Establishment and Validation of Method No. 5123 for the Analysis of 2,4-DP-p Ethylhexyl Ester in Water and Determination of the Water Solubility, DACO: 8.2.2
1094793	2005, Product Identification, DACO: 3.1.1,3.1.2,3.1.3,3.1.4 CBI
1094794	2005, Product Chemistry, DACO: 3.2.1,3.2.3,3.3.1 CBI
1094795	2002, Product anaylysis, DACO: 3.4 CBI
1094796	2005, Chemical and Physical Properties, DACO: 3.5 CBI
1284560	2004, Validation of HPLC Method for the Optical Ratio of Optica Trio, DACO: 3.4.1 CBI
1284561	2004, Validation of HPLC Method for CMPP-p/MCPA/2,4-DP-p/DMA/130/160/310 g/L, DACO: 3.4.1 CBI

Dichlorprop-P 2-EHE

PMRA Document Number	Reference
1093712	2000, DP-p 2EHE Technical. Manufacturer and Product Identity, DACO: 2.1,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9 CBI
1093713	2000, Marks DP-p 2EHE Technical. Manufacturing Methods for Technical Active Ingredient, DACO: 2.11 CBI
1093714	2000, Sections 2.12 & 2.13. Marks DP-p 2EHE Technical. Specifications/Quality Control/Analysis, DACO: 2.12,2.13 CBI
1093715	2000, Section 2.14. Marks DP-p 2EHE Technical. Chemical and Physical Properties, DACO: 2.14 CBI
1098612	2001, Development and Validation of an Analytical Method for the Determination of Mecoprop-P (MCPP-P) and Dichlorprop-P (2,4-DP-P) in Soil, DACO: 8.2.2.1,8.2.2.2
1098614	2000, Analtical Methodology-Water, DACO: 8.2.2.3
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2.0 Human and Animal Health

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3.0 Environment

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4.0 Value

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B. Additional Information Considered

i) Published Information

1.0 Environment

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